In The

Supreme Court of the United States

October Term, 1979

No. 79-731

PORTER & DIETSCH, a corporation, WILLIAM H. FRASER, individually and as an Officer of said corporation, KELLY KETTING FURTH, a corporation, and JOSEPH FURTH, individually and as an officer of said corporation,

Petitioners,

vs.

FEDERAL TRADE COMMISSION,

Respondent.

PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE SEVENTH CIRCUIT

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Petitioners pray that a writ of certiorari be issued to review the judgment of the United States Court of Appeals for the Seventh Circuit entered in the above-entitled case on August 8, 1979, which affirmed an order of the Federal Trade Commission (the "Commission") dated December 20, 1977.

CITATIONS TO OPINION BELOW

The opinion of the Court of Appeals for the Seventh Circuit, not yet officially reported, is set forth in Appendix A.

The record of the administrative proceedings before the Commission is officially reported at 90 FTC 770, *et seq.* all of which is set forth at Appendix B as follows:

Complaint (29a), Initial Decision (37a), Final Order (141a), Separate Statement of Commissioner Collier in which Commissioner Clanton concurs (145a), Opinion of the Commission (115a).

JURISDICTION

The judgment of the United States Court of Appeals for the Seventh Circuit was entered on August 8, 1979. The jurisdiction of this Court is invoked under 28 U.S.C. §1254(1).

QUESTIONS PRESENTED

1. Whether the Federal Trade Commission has statutory authority, consistent with the free speech and due process provisions of the First and Fifth Amendments respectively, to issue a cease and desist order which requires petitioners to place in all advertising, in print at least as large as the largest print appearing in the advertisement, a statement as follows:

"DIETING IS REQUIRED"

and

"WARNING: THIS PRODUCT POSES A SERIOUS HEALTH RISK FOR USERS WITH HIGH BLOOD PRESSURE, HEART DISEASE, DIABETES AND THYROID

DISEASE. READ THE LABEL CAREFULLY BEFORE USING".

✓ 2. Whether the Federal Trade Commission has statutory authority, consistent with the free speech and due process provisions of the First and Fifth Amendments respectively, to issue a cease and desist order which requires petitioners, as a condition of its right to advertise its over-the-counter drug product, to establish by scientific and clinical testing, that its product is effective for its intended use, where the Food and Drug Administration Over-the-Counter Miscellaneous Internal Drug Panel and prior cases adjudicated by the Commission and Postal Service have determined that the drug product in issue herein is effective for its intended use.

✓ 3. Whether the principles of collateral estoppel as enunciated in *Parklane Hosiery Co. v. Shore*, 439 U.S. 322, 99 S. Ct. 645 (1979) and other applicable Supreme Court cases, apply to estop the Commission from relitigating issues determined adversely to it by the Commission itself and other coordinate agencies of the federal government. 47 LW 4079

✓ 4. Whether, consistent with the due process provision of the Fifth Amendment, two Commissioners who joined the Federal Trade Commission subsequent to the submission of petitioners' appeal to a duly constituted quorum of three Commissioners, can override a 2 to 1 decision in favor of petitioners and thereby cause the Commission to rule against petitioners 3 to 2.

CONSTITUTIONAL PROVISIONS AND STATUTES

The constitutional provision involved herein are the First and Fifth Amendments to the Constitution of the United States.

The statutory provisions involved herein are the Federal Trade Commission Act, §5, 15 U.S.C. §45 and the Federal Advisory Committee Act, 5 App. I (Supp.). All of the above-referenced provisions are set forth in Appendix C.

STATEMENT OF THE CASE

Petitioner Porter & Dietsch is a Minnesota corporation which markets an over-the-counter (OTC) drug product for weight loss, known as the X-11 Plan, consisting of tablets, each containing 25 milligrams (mgs.) of a recognized appetite suppressant, phenylpropanolamine hydrochloride, and 25 mgs. of caffeine, among other ingredients.[1] Along with each bottle of tablets the consumer is given a suggested dietary regimen to follow. The company markets its product by mail order and through retail stores.[2] Petitioner Kelly Ketting Furth of Chicago, Illinois, was the advertising agency responsible for placing X-11 advertising and petitioner Joseph Furth was the account executive responsible for the X-11 account.

The Commission served a complaint pursuant to 15 U.S.C. §45, alleging that petitioners' advertising for X-11 was false and misleading in that:

> "1. Readers were led to believe that they could use X-11 and thereby lose weight without consciously reducing their caloric intake and without consciously changing their eating habits;
>
> 2. Readers were led to believe that petitioners had reasonable substantiation for claiming that on the basis of scientific evidence in its possession, substantially all users of X-11 would lose a significant amount of weight;

1. Vitamin A, Vitamin B, Vitamin B2, Vitamin B6, Vitamin C, Calcium Pantothenate, Niacinimide, Vitamin E, Vitamin B12, Methylcellulose.

2. The retail drug chain, Pay 'N Save, Inc., was a co-respondent in the Commission proceeding and in the appeal to the Seventh Circuit Court of Appeals. The Commission order entered against Pay 'N Save was affirmed as modified by the Court of Appeals. A petition for reargument filed by Pay 'N Save was denied October 16, 1979. (*See* Appendix A, page 28a).

> 3. Petitioners' advertising failed to disclose that X-11 should not be taken by persons with high blood pressure, heart disease, diabetes, or thyroid disease except as directed by a physician; and
>
> 4. The advertising failed to disclose that a diet was included in the package with a recommendation that consumers follow it."

The Commission order upheld by the Seventh Circuit[3] requires petitioners to state in any future advertising for X-11 the following, *in print as large as the largest type in the ad:*

> "DIETING IS REQUIRED"
>
> and
>
> "WARNING: THIS PRODUCT POSES A SERIOUS HEALTH RISK FOR USERS WITH HIGH BLOOD PRESSURE, HEART DISEASE, DIABETES AND THYROID DISEASE. READ THE LABEL CAREFULLY BEFORE USING."

The Commission and court upheld the warning requirement apparently on the theory that many people who suffer from the diseases mentioned in the warning tend to be overweight, but the record contains no evidence that any consumer of X-11 was ever harmed by petitioners' product or by the use of the dozens of similar products sold by petitioners' competitors.[4] Indeed, the FDA's Over-the-Counter Internal

3. Following the Commission decision, petitioners appealed to the United States Court of Appeals for the Seventh Circuit pursuant to the judicial review provisions of 15 U.S.C. §45(c) (1970).

4. Advertisements by petitioners' competitors are not required to contain the warning statement. As discussed *infra,* it is for this reason that Commissioners Collier and Clanton, comprising a majority of the Commission

(Cont'd)

Miscellaneous Drug Panel has recently affirmed the safety of the product and determined that there were no significant adverse side effects in over 40 years of phenylpropanolamine use.

Petitioners' proof showed that phenylpropanolamine is a safe and effective appetite suppressant and weight loss aid and has been so held in the past in cases involving identical products and similar advertising by a Commission Hearing Examiner,[5] the Postal Service,[6] and by the aforementioned Food and Drug Administration Over-the-Counter Internal Miscellaneous Drugs Panel.[7] The cited administrative agency cases had affirmatively found that a warning in advertising phenylpropanolamine for weight loss was not required, and that a caution statement on the label of the product pursuant to FDA regulation 21 C.F.R. §369.20 was sufficient notice to any overweight persons having the conditions mentioned in the warning.[8]

(Cont'd)
quorum to whom the agency appeal was submitted dissented from the decision of the subsequently enlarged Commission.

5. *Alleghany Pharmacal Corp.*, 75 F.T.C. 990 (1969), *reopening* 55 F.T.C. 705 (1958).

6. *Hanover House and Romar Sales,* Postal Service Docket Nos. 2/143 and 2/149 (Judicial Officer December 5, 1975) (consolidated for trial).

7. The Review Panel procedure in which petitioners' product was voted "Category I", "generally recognized as safe and effective" for weight loss, has been upheld and affirmed by the Supreme Court as the accepted method by which the Food and Drug Administration, the agency with primary responsibility for determining the safety and efficacy of drugs, is to determine such questions based upon "adequate and well-controlled clinical tests" and other appropriate data. *Weinberger v. Hynson, Westcott and Dunning, Inc.*, 412 U.S. 609 (1973); *Cutler v. Kennedy,* No. 77-0734 (D.D.C. July 16, 1979).

8. 21 C.F.R. §369.20 (1978) provides, *inter alia,* "PHENYLPROPANOLAMINE HYDROCHLORIDE PREPARATIONS, ORAL. *Caution* — Individuals with high blood pressure, heart disease, diabetes, or thyroid disease should use only as directed by physician."

Phenylpropanolamine hydrochloride, sold over-the-counter in the United States since the 1930's, is included as an ingredient not only in numerous weight loss products, but also in such heavily advertised products as Dristan, Contac, and Sine Aids. The Commission order makes petitioners the only advertisers in the United States required to place a warning in its advertisements for its OTC phenylpropanolamine product. Indeed, we believe that a safety warning is not required by the FTC in advertisements for any OTC drug product. The Seventh Circuit, in upholding the Commission order, did not deal with the patently discriminatory aspect of the Commission order and apparently approved it merely because the Commission issued it.

The Commission order also requires that petitioners not make any performance claim for *any* food, drug, device or cosmetic, *whether true or not,* unless petitioners have in their possession, "full and complete substantiation" of such claims through competent scientific tests or clinical tests (Appendix B, page 142a). However, the substantiation requirement for petitioners' product claim, which was the predicate for this portion of the Commission order, had already been established not only by the FDA OTC Panel but by the previously adjudicated Postal Service and Commission decisions.

While upholding this provision of the Commission's order, even the Court of Appeals acknowledged that it was uncomfortably close to an unconstitutionally impermissible "fencing-in" provision (Appendix A, page 19a).

Similarly, the Commission held that a user of X-11 required conscious "strict dieting" in order to lose weight, and it required petitioners to include such a statement in future advertisement (Appendix B, page 143a), even though the FDA Miscellaneous Internal Drug Panel, and the prior adjudicated agency cases had ruled that the product was effective for weight loss without the necessity of strict or conscious dieting. The rationale for these rulings was that, since phenylpropanolamine was an effective appetite suppressant, conscious dieting was not necessary in

order to lose weight. In this respect it is significant to note that in *Carlay Co. v. FTC,* 153 F.2d 493 (7th Cir. 1946), the Seventh Circuit applied this very rationale to vacate a Commission order.

The Seventh Circuit also rejected the findings of safety and efficacy made by the FDA Panel on the ground that that government agency's reaffirmation of safety and efficacy of phenylpropanolamine came "too late" (Appendix A, page 12a). The court's ruling is clearly erroneous because the Panel recommendation was based upon pre-existing clinical studies and data.

As to petitioners' collateral estoppel defense, the Court of Appeals held that the government is not precluded from relitigating medical issues where knowledge is constantly changing, citing *FTC v. Raladam,* 316 U.S. 149 (1942). This ruling is likewise incorrect. The Commission made no showing on this record that medical "knowledge" had changed to the detriment of petitioners; rather, the "additional" knowledge articulated by the FDA Panel report merely reinforced the prior medical knowledge and agency rulings that phenylpropanolamine was a safe and effective OTC weight loss product.

This case also presents a significant due process issue not heretofore considered by this Honorable Court. The issue arises from the following facts:

Following the ruling against petitioners by the Administrative Law Judge, the petitioners appealed to the then duly constituted members of the Commission.

At the time the appeal was submitted, the Commission consisted of Commissioners Dixon, Clanton and Collier. Commissioner Dole, previously active as a Commissioner, had taken a leave of absence to campaign for her husband, the Republican vice-presidential candidate, while Chairman

Pertschuck had not yet been appointed to the Commission. As such, a Commission quorum consisting of Commissioners Collier, Clanton and Dixon heard the appeal in September 1976. Almost a year later, the case remained *sub judice* and no decision had yet been rendered.

In June 1977, petitioners were advised that Chairman Pertschuck, who had been appointed in the interim, intended to participate in the decision of the case. In July 1977, petitioners filed formal written objections to the participation of Chairman Pertschuck, and also objected to the participation of Commissioner Dole, who, after the submission of petitioners' appeal to the three-member quorum, had by that time rejoined the Commission following the presidential elections.

Petitioners' objection was overruled by the Commission on the ground that absent Commissioners could participate in the decision of a case, citing 16 C.F.R. §3.52(f), which states in part:

> "[A] member of the Commission absent from an oral argument may participate in the consideration and decision of the appeal in any case in which the oral argument is stenographically reported."

Most significantly, the Commission decision overruling petitioners' objection was made with the participation and concurrence of the very two Commissioners whom the petitioners sought to disqualify. Of equal significance, upon publication of the Commission's final decision herein, it became evident that the Commission quorum to whom the appeal had been submitted had actually ruled 2 to 1 in favor of the petitioners' position on the warning issue.[9] Moreover, since the final decision had not been rendered until January 1978, it

9. See separate statement of Commissioners Collier and Clanton, Appendix B, page 145a).

further appeared that the decision had been *sub judice* for almost 18 months, apparently long enough to permit Commissioners Pertschuck and Dole to alter the outcome of the Commission quorum adversely to petitioners.

The Seventh Circuit held that even though Commissioner Dole had been a non-member of the Commission by virtue of her political leave of absence, she was merely an "absent" Commissioner under 16 C.F.R. §3.52(f), and therefore eligible to participate in the decision of this case (Appendix A, page 3a).

As to Commissioner Pertschuck, who was not a Commissioner until after the submission of petitioners' appeal, the Seventh Circuit held that he could nevertheless participate because no constitutional or statutory right of oral argument in favor of petitioners had been violated (Appendix A, page 5a)..

REASONS FOR GRANTING THE WRIT

I.

CERTIORARI SHOULD BE GRANTED TO DEFINE THE SCOPE OF THE FEDERAL TRADE COMMISSION'S AUTHORITY CONSISTENT WITH THE FREE SPEECH AND DUE PROCESS PROVISIONS OF THE FIRST AND FIFTH AMENDMENTS RESPECTIVELY, TO ISSUE A CEASE AND DESIST ORDER REQUIRING A LARGE TYPE-SIZE DISCLOSURE IN ADVERTISING WHICH IS BASED UPON FINDINGS IN CONFLICT WITH THE FINDINGS OF OTHER FEDERAL AGENCIES INVOLVING THE IDENTICAL ISSUES AND WHICH CONSTITUTES A PRIOR RESTRAINT BY EFFECTIVELY FORECLOSING PETITIONERS FROM ADVERTISING THEIR PRODUCT.

A. The Warning Notice

Significant questions are presented concerning the scope of First Amendment protection to be accorded to truthful commerical speech and the scope of the Commission's authority to issue remedial orders which effectively prohibit an advertiser from engaging in truthful advertising of a product.

An unnecessary "WARNING" and "DIETING" notice in print at least as large as the largest print appearing in the advertisement effectively bans petitioners from engaging in any advertising of its product. The "WARNING" and "DIETING" type-size requirement clearly violates petitioners' First Amendment rights, operating as a freeze against any future advertising; and it also violates the standard heretofore upheld for affirmative disclosure in *National Commission on Egg Nutrition v. F.T.C.*, 570 F.2d 157 (7th Cir. 1977), *cert. denied*, ___ U.S. ___, 99 S. Ct. 86 (1978); and *Warner-Lambert Co. v. F.T.C.*, 562 F.2d 749 (D.C. Cir. 1977), *cert. denied*, 435 U.S.

950 (1978). In those cases, the type-size standard was merely "clear and conspicuous" disclosure, *National Commission,* 570 F.2d at 160; *Warner-Lambert,* 562 F.2d at 753, and was imposed because of a finding that no less a remedy could correct consumer impressions based upon massive advertising of false representations. *National Commission,* 570 F.2d at 165; *Warner-Lambert,* 562 F.2d at 762-63. Here, there were no such findings. Indeed, the Commission imposed the "WARNING" and "DIETING" requirement despite findings of safety and efficacy of petitioners' product in previously litigated cases, and the Seventh Circuit affirmed despite a finding by an FDA panel that the product is safe and effective for weight loss without regard to dieting.

Clearly, the Commission order in this case is not merely a restriction upon "false, deceptive and misleading advertising" which requires corrective measures by affirmative disclosure; rather, the present order is, for all practical purposes, an absolute prohibition against any X-11 advertising even though truthful. This is not a "reasonable prior restraint" on commercial speech, referred to with approval as a valid theoretical possibility in cases such as *Friedman v. Rogers,* ___ U.S. ___, 47 U.S.L.W. 4151, 4153-54 (1979); *Virginia State Board of Pharmacy v. Virginia Citizens Consumer Council, Inc.,* 425 U.S. 748, 770-772 (1976); and *Bates v. State Bar of Arizona,* 433 U.S. 350, 383-384 (1977). This is an absolute prior restraint, the death knell to any X-11 advertising by petitioners. There is no way petitioner can overcome the shock and dismay to its potential customers who may wish to buy its safe and effective drug product when they see an ad containing a health warning and "DIET" notice as large as the largest type in the ad. To impose such a requirement for the advertising of an admittedly safe and effective over-the-counter appetite suppressant drug, which has been on the market since the 1930's, is without reason and represents a callous disregard for petitioners' First and Fifth

Amendment rights.[10] It is simply out of any reasonable proportion to any violation of law.

Certiorari will enable this Court to clarify and set the limits upon affirmative disclosures in commercial advertising where the effect may be to preclude even truthful advertising and to reconcile the apparently conflicting perception of such limits articulated by the Court of Appeals for the District of Columbia Circuit in *Warner-Lambert Co.,* and the Seventh Circuit herein. The problem of the limits on the FTC's power with regard to affirmative disclosure in commercial advertising is a recurring problem certain to continue.

B. Substantiation

The Seventh Circuit concedes that the order provision requiring petitioners to have in its possession "competent scientific tests" before it can make even admittedly truthful product claims, is "as extreme a fencing in provision as we would sustain" (Appendix A, page 19a). Petitioners believe that the "fencing in" provision is unconstitutionally "extreme", violating petitioners' First and Fifth Amendment rights, because the FDA OTC Panel, a panel of government recognized experts established pursuant to congressional enactment, has already confirmed, based upon adequate, well-controlled clinical tests and other accepted scientific data, that petitioners' drug product is safe and effective for weight loss.

The Commission order, if upheld, would prohibit admittedly truthful claims merely because petitioners do not have in their possession full and complete substantiation satisfactory to the FTC. The fact is, however, that such substantiation already exists by virtue of the FDA Panel findings. The Court of Appeals' refusal to accept such findings and to require petitioners to conduct needless tests is a clear

10. Even in the case of cigarettes, a proven killer, the FTC has not required the Surgeon General's warning to be in type-size equal to the largest type appearing in the ad. The FTC recognizes the obvious – such a requirement effectively prohibits all advertising.

violation of the Federal Trade Commission Act and, as applied to the facts of this case, a violation of the First and Fifth Amendments. Moreover, this is a problem of recurring significance in that the FTC has repeatedly invoked its "substantiation" requirement as a precondition to a company's right to advertise, regardless of the truth or falsity of its claims. *See, e.g., Jay Norris, Inc. v. F.T.C.*, 598 F.2d 1244 (2d Cir. 1979), *petition for cert. filed,* No. 79-434 (September 14, 1979); *Firestone Tire and Rubber Co. v. F.T.C.*, 481 F.2d 246 (6th Cir. 1973), *cert. denied,* 414 U.S. 1112 (1973); *Sears Roebuck & Co.*, F.T.C. Docket No. 9104 (A.L.J. October 11 1979); *National Dynamics, Inc.*, 82 F.T.C. 488 (1973); *Pfizer, Inc.*, 81 F.T.C. 23 (1972). The instant case provides the Supreme Court with an opportunity to clarify the law for regulators and advertisers alike.

II.

CERTIORARI SHOULD BE GRANTED TO DEFINE THE SCOPE OF COLLATERAL ESTOPPEL IN ADMINISTRATIVE PROCEEDINGS.

The Seventh Circuit rejected petitioners' collateral estoppel defense on the ground that the government is not bound by prior decisions involving questions of pharmacological science and can relitigate identical issues against the same or different parties in subsequent cases without qualification. Although the court grounded its holding on the presumption that pharmacology is an area where knowledge is "constantly advancing", they did not require the Commission to make even a *prima facie* showing that such knowledge had, in fact, changed in favor of the government's position in this case. Without such a showing, the Seventh Circuit's holding clearly violates the rule in favor of repose established by this Court in such cases as *Montana v. United States,* ___ U.S. ___, 99 S. Ct. 970 (1979); *Parklane Hosiery Co. v. Shore,* ___ U.S. ___, 99 S. Ct. 645 (1979); *Blonder-Tongue Laboratories, Inc. v. University of*

Illinois Foundation, 402 U.S. 313 (1971) and *United States v. Utah Construction and Mining Co.*, 384 U.S. 394 (1966). If the Seventh Circuit ruling is allowed to stand, it could lead to numerous cases in which the government will continuously relitigate its lost causes, even though advancing medical knowledge may not have altered the effect of previous rulings.

The Seventh Circuit's reliance on *FTC v. Raladam,* 316 U.S. 149 (1942) is misplaced. In the *Raladam* case, this Court held that the FTC could relitigate the same issue against the same party *based on new facts,* even though its previous order was denied enforcement. 316 U.S. at 150-151. In the present case, however, there was no attempt to relitigate an issue based on new facts. Rather, the Commission here sought to relitigate the issues of safety and efficacy of phenylpropanolamine, which were previously determined adversely to the government, not only by the Postal Service proceeding in *Hanover House and Romar Sales,* but by a Commission proceeding as well. *Alleghany Pharmacal Corp.* Moreover, these adverse rulings were reaffirmed by a panel of FDA appointed medical experts, constituted pursuant to the provisions of the Federal Advisory Committee Act, who found phenylpropanolamine safe and effective for weight loss without reference to conscious dieting. Thus, the Seventh Circuit decision herein compromises the authority of the FDA, the agency primarily responsible for the determination of the safety and efficacy of drugs, and thereby subjects petitioners to a "substantial danger" of "duplicative and inconsistent standards", condemned by this Court in *United States v. National Association of Securities Dealers,* 422 U.S. 694, 729-730, 735 (1975).

In this connection, the decision of the Seventh Circuit herein is at variance with a line of cases in the Seventh and other circuits holding that the United States government and its instrumentalities, including the Commission, are not entitled to argue that safety and efficacy representations, which have been adjudged not to be false, are in fact false, because after the

government has had its full day on these issues and lost, it cannot collaterally attack, directly or indirectly, the prior determination against it. *See Sunshine Anthracite Coal v. Adkins,* 310 U.S. 381, 403 (1940); *F.T.C. v. Texaco, Inc.,* 517 F.2d 137, 147 (D.C. Cir. 1975), *cert. denied,* 431 U.S. 974 (1977); *United States v. Willard Tablet Co.,* 141 F.2d 141 (7th Cir. 1944); *George H. Lee Co. v. F.T.C.,* 113 F.2d 583 (8th Cir. 1944); *United States v. 14 Cartons, More or Less . . . Ayds,* No. 3736 (E.D. Mo. June 10, 1946) [not officially reported, but reprinted in (1938-1949) Kleinfeld and Dunn, Federal Food, Drug, and Cosmetic Act 182 (1949)].

Review by this Court presents the opportunity to reconcile the various court decisions regarding the extent to which the principle of collateral estoppel, as enunciated in *Parklane Hosiery Co. v. Shore,* is applicable to prevent different federal agencies from relitigating and making contradictory findings on the same issue.

III.

CERTIORARI SHOULD BE GRANTED TO DETERMINE WHETHER A QUORUM OF ADMINISTRATIVE AGENCY MEMBERS HEARING A CASE CAN BE OVERRIDDEN BY AGENCY MEMBERS WHO REJOIN OR WHO ARE APPOINTED TO SUCH AGENCY SUBSEQUENT TO THE SUBMISSION OF THAT CASE TO THE AGENCY.

This case presents the significant question of when and to what extent subsequently appointed Commissioners of the FTC may participate in deciding an appeal which has previously been submitted to a duly constituted quorum of the Commission. The circumstances of the present case are particularly egregious in that the quorum which heard petitioners' appeal actually ruled in petitioners' favor on a crucial issue, but their decision was then overridden by the participation of two subsequently

appointed Commissioners. This issue has never previously been decided by this Court and involves a matter of major due process rights to all litigants before the Commission.

In rejecting petitioners' argument on this point, the Court of Appeals below improperly focused upon whether a respondent in an FTC proceeding is entitled to oral argument as a matter of constitutional or statutory right. The court's reasoning missed the mark, although it should be noted that while oral argument is not mandated by *statute,* it is mandated by the Commission's own Rules of Practice, 16 C.F.R. §3.52(f) (1978). What is involved, however, is not merely whether oral argument is a matter of statutory right, but whether a duly constituted quorum of Commissioners, charged by statute with performing adjudicative functions and sitting as a judicial tribunal, may be enlarged after submission of an appeal in a manner which makes possible a different decision from that which the original tribunal would have rendered. In fact, the issue presented is whether a judicial tribunal may be "packed" by subsequent appointees to alter the outcome of a case which is *sub judice* before the tribunal. Petitioners submit that if this practice remains unchallenged, the integrity of the judicial process itself will become seriously suspect. In proceedings before a judicial tribunal, even the mere appearance of impropriety must be avoided, if respect for the judicial process is to be honored and enhanced.[11] The present case is merely another example of the type of frequently recurring improprieties by members of the Federal Trade Commission, which various courts have been called upon to correct in order to safeguard the integrity of proceedings before that agency. *American Cyanamid Co. v. F.T.C.,* 363 F.2d 757 (6th Cir. 1966); *Association of National Advertisers v. F.T.C.,* 460 F. Supp. 996 (D.D.C. 1978); *see also, Amos Treat & Co. v. S.E.C.,* 306 F.2d 260 (D.C. Cir. 1962). The instant case, therefore, presents this Honorable Court with the

11. The 18-month delay between the submission of the appeal to the Commission and the final decision lends emphasis to the suspect nature of the entire proceeding.

opportunity to define the limits beyond which Commissioners may not go in adjudicating issues over a respondent's timely objection that became *sub judice* prior to the commencement of the Commissioner's status as a "judge".

In the present case, over the timely objection of petitioners, not only were Commissioners, who joined or rejoined the Commission after the case was submitted to a duly constituted quorum of Commissioners, allowed to participate in the decision, they changed the outcome of the case. The prejudice to petitioners from such action is particularly grievous, because the warning requirement imposed upon petitioners as a result of the participation by the two added "Commissioners" has the practical effect of putting petitioners out of business. We respectfully submit that the procedures invoked against petitioners in this case could never pass muster in any judicial proceeding presided over by the Honorable Justices of this or any other appellate tribunal. The defect in the present case is apparent on its face, *see WIBC, Inc. v. F.C.C.*, 259 F.2d 941 (D.C. Cir.), *cert denied sub nom. Crosley Broadcasting Corp. v. WIBC*, 358 U.S. 920 (1958), and justifies a reversal on the "warning" aspect of the Commission's order, without the necessity either for further briefing or a full Supreme Court hearing.

CONCLUSION

For all the foregoing reasons, the petition for certiorari should be granted.

Respectfully submitted,

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APPENDIX A — OPINION OF THE UNITED STATES COURT OF APPEALS FOR THE SEVENTH CIRCUIT, *PORTER & DIETSCH, INC., ET AL. v. FEDERAL TRADE COMMISSION*, NOT OFFICIALLY REPORTED

In the

United States Court of Appeals

For the Seventh Circuit

Nos. 78-1324 and 78-1497

PORTER & DIETSCH, INC., a corporation, WILLIAM H. FRASER, individually and as officer of said corporation, KELLY KETTING FURTH, INC., a corporation, and JOSEPH FURTH, individually and as officer of said corporation, and PAY'N SAVE CORPORATION,

Petitioners,

v.

FEDERAL TRADE COMMISSION,

Respondent.

Petitions for Review of Orders of the Federal Trade Commission

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ARGUED JANUARY 9, 1979—DECIDED AUGUST 8, 1979

Before PELL and TONE, *Circuit Judges*, and KIRKLAND, *District Judge.**

TONE, *Circuit Judge.* This case comes to us on a petition to review a Federal Trade Commission false advertising order relating to non-prescription weight reducing

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* Judge Alfred Y. Kirkland of the Northern District of Illinois sat on this case at the time of oral argument by designation. On May 1, 1979, Judge Kirkland became a senior district judge of the Northern District of Illinois and is continuing to sit on this case by redesignation.

tablets.[1] Petitioners raise a variety of issues, which include the propriety of participation in the decision by two of the commissioners, collateral estoppel, sufficiency of the evidence, procedural due process, and the appropriateness of the relief granted. We approve the order with minor exceptions.

Petitioners are Porter & Dietsch, Inc., which packages the subject "X-11" tablets and sells them through retail drug stores and the mail; William Fraser, its president and sole shareholder; Kelly Ketting Furth, Inc., its advertising agency; Joseph Furth, the agency's account executive responsible for X-11 advertising; and Pay'n Save Corporation, a retail drug store chain that sells X-11 tablets. All petitioners except Pay'n Save took an active role in the creation of the advertisements in question and were aware that representations in them posed potential legal problems. Pay'n Save's only connection with the X-11 advertising was its participation in Porter & Dietsch's co-operative advertising programs, through which it received advertising materials and instructions for their publication from Porter & Dietsch, and caused them to be published bearing Pay'n Save's name. Nothing in the record indicates that Pay'n Save had any knowledge that the representations in the advertisements were false or unsubstantiated.

After an evidentiary hearing, an FTC Administrative Law Judge rendered an initial decision finding that petitioners had made the following representations in their advertising, as the FTC complaint had alleged:

1) Users of X-11 tablets can lose weight without restricting their accustomed caloric intake and while they continue to eat the foods of their choice.

2) Petitioners have a reasonable basis from which to conclude that substantially all users of X-11 tablets will lose a significant amount of weight.

3) The X-11 tablet contains a unique ingredient.

[1] Porter & Dietsch labelled and advertised the product as the "X-11 Reducing Plan," but for reasons discussed *infra* at note 4, we agree with the Commission that the advertised product was the tablets.

In addition, the ALJ found, petitioners omitted the following material facts from their X-11 advertisements:

1) The typical and ordinary experiences of consumers do not parallel the experiences reported in testimonials appearing in the advertisements.

2) Persons with high blood pressure, heart disease, diabetes, or thyroid disease should only use X-11 tablets as directed by a physician.

3) A low-caloric diet is a part of the X-11 plan.

The ALJ found that these representations and omissions were false and misleading and constituted unfair and deceptive acts and practices in violation of §§ 5 and 12 of the Federal Trade Commission Act (15 U.S.C. § 45 and 52). On appeal to the Commission, the ALJ's proposed findings, conclusions, and recommended order were adopted with minor modifications.

I.

Participation in the Decision by Commissioners Who Were Not Active Commissioners at the Time of Oral Argument.

Petitioners' first contention is that two of the five commissioners of the FTC should not have participated in the decision. Only three commissioners were present at the oral argument before the Commission on September 29, 1976. At that time Commissioner Dole was on leave of absence because of her husband's candidacy for Vice-President of the United States, and Chairman Pertschuk was not yet a member of the Commission. Commissioner Dole resumed her duties as a commissioner and Chairman Pertschuk assumed his office many months before the case was decided.

Commissioner Dole remained a commissioner throughout the period of her leave. 16 C.F.R. § 3.52(f), which gives the FTC discretion to decide any case without oral argument, states:

[A] member of the Commission absent from an oral argument may participate in the consideration and

> decision of the appeal in any case in which the oral argument is stenographically reported.

The oral argument before the Commission in this case having been stenographically recorded, Commissioner Dole was permitted by rule to participate in the decision.

Petitioners argue that Chairman Pertschuk was not similarly covered by the rule, because he was not a member of the Commission at the time of oral argument. If one in his position could participate, they argue, the President could "pack" the Commission, and also it would be impossible for litigants to frame contentions "in reliance" on the existing composition of the Commission. Neither argument is persuasive. Even if we were willing to assume a President would act in bad faith, which we are not, prohibiting a commissioner appointed after oral argument from participating in the decision would not solve the problem. Nothing would prevent the Commission, after the addition of the new member, from ordering reargument or from rehearing the case after it was decided. As for the reliance argument, a litigant has no cognizable interest in the composition of the tribunal that will decide his case and is entitled only to impartiality in that tribunal. *Cf. Friedman v. Rogers*, ... U.S. ....., 99 S.Ct. 887, 898 (1979).

The District of Columbia Circuit held in *Gearhart & Otis, Inc. v. SEC*, 348 F.2d 798 (D.C. Cir. 1965), that participation in a decision by a member of the Securities and Exchange Commission appointed after oral argument was proper when the parties had agreed to that participation. The court then added:

> The decisions of numerous courts and administrative agencies establish that, even without agreement of the parties, a member of an administrative agency who did not hear oral argument may nevertheless participate in the decision where he has the benefit of the record before him.

348 F.2d at 802 (footnotes omitted); *see id.* at nn. 12 & 13. The court distinguished its earlier decision in *WIBC, Inc. v. FCC*, 259 F.2d 941 (D.C. Cir.), *cert. denied sub nom.*

Crosley Broadcasting Corp. v. WIBC, Inc., 358 U.S. 920 (1958), on which petitioners in the case at bar rely, on the ground, not only that there was no comparable waiver in that case, but that the Communications Act, 75 Stat. 422, 47 U.S.C. § 409(b), requires oral argument. *See* 348 F.2d at 802 n.14. The FTC is not similarly restricted by statute and has a rule, 16 C.F.R. § 3.52(f), quoted above, permitting participation in the decision by a commissioner who was not present at oral argument. In *Au Yi Lau v. United States Immigration and Naturalization Service*, 555 F.2d 1036, 1042 (D.C. Cir. 1977), the court affirmed an agency decision even though a majority of the participating members became members of the agency after the oral argument. *Accord, Arthur Lipper Corp. v. SEC*, 547 F.2d 171, 182 n.8 (2d Cir. 1976), *cert. denied*, 434 U.S. 1009 (1978).

The participation of Chairman Pertschuk and Commissioner Dole in the decision of the case at bar was proper.

II.

Confusion of the Issues.

Petitioners allege that they were misled to their detriment by the statements made during the hearing by the ALJ and complaint counsel concerning the relevance of whether the principal ingredient of X-11 tablets, phenylpropanolamine hydrochloride (PPA), is an effective appetite suppressant.

Some confusion as to the relevance of the efficacy of PPA did exist at the hearing. The ALJ correctly stated, however, that the issue was the veracity of the representations made in the X-11 tablets advertisements, and that the efficacy of PPA was relevant only for its hearing on whether X-11 fulfilled those representations. Although petitioners contend that they were misled by the confusion and were unable effectively to cross-examine the Commission's expert witness on the efficacy of PPA, the record shows the contrary. Petitioners did cross-examine the experts on the efficacy of PPA and were not hampered in any way in their

cross examination. In addition, the record also contains numerous studies and excerpts from learned treatises on this subject. As the Commission correctly held, petitioners were not misled in the manner alleged.

III.

Collateral Estoppel.

Petitioners argue that determinations of fact made in three prior administrative proceedings preclude relitigation of the controlling issues here. The three decisions relied upon are *In re Alleghany Pharmacal Corp.*, 75 F.T.C. 990 (1969), and two Postal Service cases, consolidated for hearing before the ALJ, *In re Hanover House* and *Romar Sales Corp.*, Postal Service Docket Nos. 2/143 and 2/149 (1975). These three cases involve allegedly false and misleading advertising for a product called "Hungrex," which is said to be virtually identical to X-11.[2] The Commission rejected the collateral estoppel argument, as do we.

The doctrine of collateral estoppel "precludes relitigation of issues actually litigated and determined in the prior suit. . . ." *Lawlor v. National Screen Service Corp.*, 349 U.S. 322, 326 (1955); *Montana v. United States*, ... U.S. ....., 99 S.Ct. 970, 973-974 (1979); *Parklane Hosiery Co. v. Shore*, ... U.S. ....., 99 S.Ct. 645, 649 n.5 (1979). The doctrine may apply even though the party asserting it was not a party in the prior case. *Parklane Hosiery Co. v. Shore, supra*, 99 S.Ct. at 649-652; *Blonder-Tongue Laboratories, Inc. v. University of Illinois Foundation*, 402 U.S. 313, 334 (1971). It may be applied to adjudicative determinations of administrative agencies. *Parklane Hosiery Co. v. Shore, supra*, 99 S.Ct. at 652; *United States v. Utah Construction & Mining Co.*,

[2] For purposes of this argument, we will assume that Hungrex and X-11 are identical products. Both are tablets containing 25 mgs. of PPA, which is the appetite suppressing ingredient that purportedly makes the product effective in weight reduction.

384 U.S. 394, 422 (1966); *Bowen v. United States*, 570 F.2d 1311, 1321 (7th Cir. 1978).

Alleghany Pharmacal involved issues different from those in the case at bar. In the two Postal Service cases the safety issue was similar to the safety issue in the case at bar.

Nonetheless, the Commission was not required to give the Postal Service decisions preclusive effect. Relitigation of an issue is not precluded even between the original parties when "[t]here is a clear and convincing need for a new determination of the issue . . . because of the potential impact of the determination on the public interest or the interests of persons not themselves parties to the initial action . . . ." *Restatement (Second) of Judgments* § 68.1(e)(i) (Tent. Draft No. 4, 1977). Comment *h* to this section of the *Restatement* gives as an example of the § 68.1(e)(i) exception an action by "an agency of government . . . for the protection . . . of a broad segment of the public." This is such a case.

This is not only a proceeding by an agency of government to protect the public from both health risks and false advertising; it deals with a body of knowledge in the fields of medical and pharmacological science that is constantly increasing. The government is not precluded from subsequently relitigating against a new respondent under these circumstances. *Cf. FTC v. Raladam Co.*, 316 U.S. 149, 150-151 (1942) (allowing the FTC to relitigate substantially the same issue against the same party where its previous order was denied enforcement because of insufficient evidence in the record); *see Montana v. United States, supra*, 99 S.Ct. at 976-977; 2 Davis, *Administrative Law Treatise* § 18.04 at 571 (1958).[3]

[3] Petitioners also refer to a Postal Service complaint issued against Porter & Dietsch for advertisements of X-11. This complaint was dismissed without prejudice pursuant to a

(Footnote continued on following page)

Appendix A

IV.

Sufficiency of the Evidence.

Petitioners assert that the findings on which the Commission based the challenged order are not supported by the evidence in the record.

"Whether particular advertising has a tendency to deceive or mislead is obviously an impressionistic determination more closely akin to a finding of fact than to a conclusion of law." *Beneficial Corp. v. FTC*, 542 F.2d 611, 617 (3d Cir. 1976), *cert. denied*, 430 U.S. 983 (1977). Giving due regard to the FTC's expertise, *FTC v. Colgate-Palmolive Co.*, 380 U.S. 374, 385 (1965), and *National Commission on Egg Nutrition v. FTC*, 570 F.2d 157, 161 (7th Cir. 1977), *cert. denied*, ... U.S. ....., 99 S.Ct. 86 (1978), we must sustain the FTC's findings if they are supported by substantial evidence on the record viewed as a whole, *Universal Camera Corp. v. NLRB*, 340 U.S. 474, 491 (1951).

Petitioners contend that in some instances the evidence does not support the finding that the representations were made as charged or that material facts were omitted. They also argue that no representation or omission was proved false or misleading. With respect to each representation we consider together the issues of whether it was made and whether it was false.

A. *False Affirmative Representations.*

1. *That users of X-11 tablets[4] can lose weight without restricting their accustomed caloric intake and while they continue to eat the foods of their choice.*

[3] *continued*
stipulation, Postal Service Docket No. 3/63 (January 5, 1976), and therefore can have no preclusive effect. *Lawlor v. National Screen Service Corp., supra*, 349 U.S. at 326.

Petitioners have not been the subject of government harassment in the form of repeated agency prosecutions.

[4] Petitioners contend here, as they did unsuccessfully before the Commission, that the product advertised was the "X-11

(Footnote continued on following page)

Appendix A

Petitioners attack this finding as inaccurate, arguing that their advertising advises the reader that the tablets function merely as an appetite suppressant which will make users "want less" and therefore "eat less." Many of the advertisements, however, proclaim in large type, "EAT WELL . . . AND LOSE THAT FAT" or "EAT WHAT YOU WANT—AND SLIM DOWN," and follow with statements that "no starvation dieting" was required and that weight could be lost without "suffering through starvation dieting hunger" or following "boring reducing diets." Other statements in the advertisements relied upon by petitioners as clarifying the matter could reasonably have been considered by the Commission to be inadequate for that purpose not only because they were buried in small print but because in any event they did not withdraw the misleading statements. The Commission properly found that the advertisements as a whole conveyed the impression to consumers that they could lose weight through the use of X-11 without changing their eating habits and without restricting their accustomed caloric intake.

The correctness of the Commission's finding that this representation was false is supported by Porter & Dietsch's own statements in a printed insert placed in each X-11 package. The insert stated that weight loss is only accomplished when a minimum of calories are consumed and set forth an "eating program for reducing overweights" which is to be used in conjunction with the

[4] *continued*
Reducing Plan." The Commission correctly found that the advertised product was the tablets, not the plan, and proceeded accordingly. The "X-11 Reducing Plan" consisted of only the tablets and a package insert which contained a proposed "eating program for overweights." This so-called program was, in the opinion of experts, a "starvation" or "near-starvation" diet. Nothing indicates that this diet would work better than any other diet X-11 users chose to follow. More important to our conclusion, the advertisements represented the product to be the tablet and did not explain what the plan entailed, beyond taking the tablets. Finally, as the Commission found, the advertisements falsely represented that dieting was unnecessary. Consequently, we too treat the product as consisting solely of the tablets.

tablets. This program, which purportedly proposes "3 sensible meals a day" was characterized by expert witnesses at the hearing before the ALJ as a "starvation" or "semi-starvation" diet. The program does not allow the consumption of any rich foods or sweets or other snacks. A number of the advertisements, in contrast, assert that users can eat snacks and still lose weight. Furthermore, it is undisputed that, as the ALJ found, the tablets will not result in weight reduction unless the user follows a severely restricted caloric diet. We have no difficulty in concluding that the Commission correctly found this representation to be false.

2. *That petitioners have a reasonable basis consisting of scientific evidence from which to conclude that substantially all users of X-11 tablets will lose a significant amount of weight.*

Although the advertisements did not state in so many words that substantially all X-11 users would lose a significant amount of weight, they are replete with testimonials claiming weight losses in excess of 40, 50, and even 80 pounds attributable to use of X-11, accompanied by such statements as, "thousands of women throughout America" are losing "5, 10, 25 or even more pounds." The large weight losses are characterized as "automatic." Adding to this impression is the invariable guarantee: "RESULTS ARE GUARANTEED—OR MONEY BACK" or "TAKE WEIGHT OFF WITH THE VERY FIRST BOX OR MONEY BACK." That this claim was represented as resting on a scientific basis appears from such statements as "Recently, laboratory science has perfected a tiny tablet . . .," "X-11 is the PROVEN and SOUND method . . .," "clinic tested ingredients," and "medically recognized as an effective plan to lose ugly fat." The Commission properly found, based on these facts, that petitioners made what amounted to a representation that they had scientific evidence proving that substantially all X-11 users would lose a significant amount of weight.

Petitioners do not deny making this representation but challenge the finding that it was false. They argue first

that "[t]here is no evidence to support the Commission's finding that 'Scientific Testing' is the only reasonable basis for substantiation of X-11 weight loss claims," and, second, that "scientific testing" supporting the claims does exist.

We need not rule on the first argument, because it is an attack on a finding the Commission did not make. While the ALJ concluded that the efficacy of a product such as X-11 could not be substantiated without scientific evidence, the Commission did not reach the issue,[5] finding it unnecessary to do so, because, even if some other reasonable basis for the claims might have existed, petitioners had represented that the basis was scientific testing. The Commission might appropriately have reached the issue decided by the ALJ in connection with the relief granted in the order but chose instead to rely on the "fencing in" doctrine. *See* Part V,B,4, *infra*, where we consider whether the provision of the Commission's order prohibiting representations about the efficacy of the product unless they are supported by "competent scientific or medical tests or studies" is sustainable.

We have examined the evidence supporting the Commission's determination that petitioners did not have scientific evidence forming a reasonable basis for the claim that substantially all X-11 users would lose significant amounts of weight, including the findings of fact from *Alleghany Pharmacal, supra*. That evidence is set

[5] The ALJ and the Commission looked to more than "scientific testing" in attempting to find a reasonable basis; they considered scientific studies and reports, medical texts and references, the testimony of medical doctors and other experts, and even the records and findings of the "Hungrex" cases, and concluded that no reasonable basis exists for the claims made here. The Commission in *In re Pfizer, Inc.*, 81 F.T.C. 23 (1972), recognized that "there may be some types of claims for some types of products for which the only reasonable basis, in fairness and in the expectations of consumers, would be a valid scientific or medical basis." 81 F.T.C. at 64. The case at bar, in which the representations concern the efficacy of a drug, is such a case.

forth in detail in the opinion of the Commission and need not be repeated here.[6]

The scientific evidence on which petitioners rely[7] provides at most a reasonable basis for the conclusion that PPA is an effective appetite suppressant for some people, helping them to lose weight if taken in conjunction with a strict diet. But the evidence falls far short of being sufficient to establish "automatic" significant weight losses for all users, as represented.

3. *That X-11 tablets contain a unique ingredient.*

The frequent references in the advertisements to a "unique formula," a "unique preparation," a "special formula," coupled with statements that "laboratory science" had "recently" or "now" developed the tablets, considered in the light of the admission of Porter & Dietsch that these statements referred to PPA, support this finding.

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[6] Petitioners urge that we take judicial notice of the fact that the Food and Drug Administration Over-the-Counter Miscellaneous Internal Drugs Panel voted PPA "safe and effective" as an appetite suppressant. Even if we could consider evidence that was not before the agency, this evidence would be of no help to petitioners. The vote was taken in August of 1978, long after petitioners made the representations in question. Moreover, the transcript of the meetings in which the FDA panel discussed the efficacy of PPA reveals that their vote would not have served as a reasonable basis for making the claims involved here even if it had come before the representations in issue were made. Although the doctors concluded that PPA is an effective appetite suppressant, they also noted that diet control is also necessary for weight reduction. Furthermore, the panel did not indicate that evidence exists from which to conclude that substantially all users of PPA will lose significant amounts of weight.

[7] One study relied on by petitioners showed "clinically insignificant" differences in weight loss between a group using PPA and a group using a placebo. The closest any evidence came to establishing the effects of PPA on "all users" was a study in the *Alleghany Pharmacal* record which showed that 80 per cent of PPA users lost significant amounts of weight. Even this would not support a claim of success for "substantially all users."

The finding that it was false is also supported. PPA has been used for years in many products, including other over-the-counter weight reduction products. Petitioners, conceding that PPA is not unique to X-11, contend that it is a unique pharmacological substance. The ALJ found this assertion to be not wholly untrue. PPA is a particularly weak member of a family of amphetamine-like drugs.[8] It produces the same types of responses as related drugs produce, but, because it is weak, it produces fewer side effects and less central nervous system stimulation and is therefore the only drug of its class available without a prescription. Nonetheless, the ALJ and the Commission believed that the public would not understand "unique" as describing this property but would interpret it, as petitioners no doubt intended, as meaning not available in other products and unequaled in efficacy and, in view of the assertions about the recent achievement of laboratory science, newly discovered. We agree with the Commission's assessment of Porter & Dietsch's shabby hucksterism; "an otherwise false advertisement is not rendered acceptable merely because one possible interpretation of it is not untrue." *National Commission on Egg Nutrition v. FTC*, *supra*, 570 F.2d at 161 n.4.

B. *Omissions of Material Facts.*

1. *The typical and ordinary experiences of consumers do not parallel the experiences reported in testimonials appearing in the advertisements.*

We have already approved the Commission's findings concerning the extravagant weight loss claims, which were conveyed in substantial part through the use of testimonials. *See* Part IV,A,2, *supra*. The Commission further found, based on ample evidence, that weight losses of the magnitude claimed, far from being typical, as the advertisements implied, are extremely rare in any diet regimen. Its holding that the failure to disclose that such losses are rare rendered the advertisements false and misleading is sustained.

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[8] The sympathomimetic amines.

2. *Persons with high blood pressure, heart disease, diabetes, or thyroid disease should only use X-11 tablets as directed by a physician.*

The ALJ found that the failure to include a health warning in the X-11 advertisements constituted an omission of material fact, and the Commission affirmed, with two commissioners dissenting. We approve the findings of the majority of the FTC.

Petitioners, except Pay'n Save, admit that PPA should not be ingested by persons with high blood pressure, heart disease, diabetes, or thyroid disease except under the supervision of a physician.[9] A warning to this effect is printed on the back of the X-11 package, in compliance with FDA Regulations, 21 C.F.R. § 369.1, *et seq.*

The erroneous impression that X-11 is safe for use by all potential consumers is created by the statement, "No dangerous drugs," the effect of which is aggravated by the statement, "Laboratory science has perfected a tiny pre-meal tablet . . . ." Petitioners sold large quantities of X-11 tablets to mail order purchasers, who would not have an opportunity to read the health warning on the package until they had already paid out their money and some of whom, having paid, would be likely to take the chance of using the tablets.

The record shows that many people suffer from the diseases PPA tends to aggravate and that many of those people are overweight. An estimated 28,410,000 persons in the United States suffered from a heart ailment or high blood pressure in 1972. Of these, 22,950,000, one out of every six adults, had high blood pressure. One out of every 20 suffered from diabetes in 1975. Furthermore,

[9] The record shows that all sympathomimetic amines, including PPA, exert a "pressor" effect, which means they cause vascular constriction. This constriction causes an elevation of the blood pressure, which is hazardous for persons already suffering from high blood pressure. The constriction also forces the heart to work harder, creating a danger for persons with heart disease. PPA also has a tendency to elevate the blood glucose level, thus aggravating diabetes in persons suffering from that disease. PPA apparently also exacerbates the effects of an overactive thyroid.

high blood pressure and heart disease occur more frequently among the overweight, and the likelihood of being diabetic more than doubles with every 20 per cent of excess weight. Thus the product and the advertising are designed for persons most likely to suffer from the serious side effects.

The finding that the failure to disclose health risks rendered the ads false and misleading is sustained.[10]

3. *A highly restricted caloric diet is a part of the X-11 plan.*

The findings we affirmed in Part IV,A,1, *supra*, also support the Commission's finding that this omission caused the advertisements to be false and misleading.

V.

Propriety of the Remedy.

A. *Standard of Review.*

The Supreme Court set forth the standard for reviewing remedial provisions of an FTC order in *Jacob Siegel Co. v. FTC*, 327 U.S. 608, 612-613 (1946):

> The Commission is the expert body to determine what remedy is necessary to eliminate the unfair or deceptive trade practices which have been disclosed. It has wide latitude for judgment and the courts will not interfere except where the remedy selected has no reasonable relation to the unlawful practices found to exist.

[10] Petitioners again point to the *ex post facto* FDA panel vote that PPA is "safe and effective." *See* note 6, *supra*. The doctors on the panel agreed, however, that because of its potential for adverse reaction, PPA has been contraindicated for persons with high blood pressure, heart disease, diabetes, and thyroid disease.

B. *Portions of the Order Applicable to Petitioners Porter & Dietsch and William Fraser.*

1. *The First Amendment.*[11]

Petitioners contend that the order violates their rights under the First Amendment, which protects "commercial speech." *Bigelow v. Virginia*, 421 U.S. 809 (1975). They concede, however, as they must, that the First Amendment allows the prohibition of false and misleading advertising. *Ohralik v. Ohio State Bar Association*, 436 U.S. 447, 455-456 (1978); *Bates v. State Bar of Arizona*, 433 U.S. 350, 381-384 (1977); *Virginia State Board of Pharmacy v. Virginia Citizens Consumer Council, Inc.*, 425 U.S. 748, 771-772 (1976); *National Commission on Egg Nutrition v. FTC, supra*, 570 F.2d at 161-162. Because the advertising material subject to the Commission's order was false and misleading, *see* Part IV, *supra*, it receives no protection from the First Amendment.

2. *Product coverage.*

Paragraph I of the order restricts the representations Porter & Dietsch and Fraser may make concerning any "food," "drug," "cosmetic," or "device" as these terms are defined in the Federal Trade Commission Act. Petitioners contend that this breadth of product coverage makes the order overly broad, because there is no rational connection between the Commission's findings and restrictions placed on representations of products other than X-11. The record shows that Porter & Dietsch is continuously testing and marketing new products and, as a wholesale operation not faced with the expense of modifying manufacturing facilities to add new products to its line, it can do so comparatively cheaply. Fraser and wholly-owned subsidiaries of Porter & Dietsch have violated the Federal Trade Commission

[11] Petitioners' assertion that the affirmative disclosures required by Paragraph I,E of the order violate the First Amendment are treated separately in Part V,B,7, *infra*.

Act in the past.[12] These facts and the evidence of petitioners' readiness, in carrying out the advertising campaign for X-11, to go at least to the very limits of what the law might be argued, with some modicum of plausibility, to allow, justified the breadth of the order against the principal offenders.

3. *Paragraph I,A.*

Paragraph I,A of the order prohibits representations that a user of a product can lose weight without restricting caloric intake and while eating the foods of his or her choice. Petitioners contend that Paragraph I,A is not supported by substantial evidence, because it is premised on the assumption that a user of X-11 must consciously restrict caloric intake and consciously avoid foods of his or her choice to lose weight. That assumption is false, they argue, because PPA is an effective appetite suppressant which unconsciously and automatically reduces food intake. Petitioners' position is untenable in light of the findings upheld in Part IV,A,1, *supra*, of this opinion. X-11 must be coupled with a conscious adherence to a restricted calorie diet to be effective and Paragraph I,A merely prohibits petitioners from making representations to the contrary. Paragraph I,A is reasonably related to the unlawful practice and is valid.

4. *Paragraph I,B.*

Paragraph I,B prohibits representations that a user of a product "can achieve any result" unless the representation is, when made, substantiated by competent

[12] *See In re Udga, Inc. and William Fraser, and Mary Fraser*, 24 F.T.C. 1245 (1937), wherein the FTC found that an antacid was being deceptively advertised as a cure for ulcers. Fraser is also subject to an FTC consent order, *In re Ru-Ex, Inc.*, 59 F.T.C. 839 (1961), which is limited to products similar to the one sold there as a remedy for arthritis or rheumatism. The Commission considered this consent order in mitigation, rather than in aggravation, on the point of the necessity of a broad order.

scientific or medical tests and studies and requires that such tests or studies, the raw data gathered, and the procedures followed, be available to the Commission for inspection for three years following the representation. Petitioners contend that Paragraph I,B improperly relieves the Commission of the burden of proving their advertising representations false and imposes on petitioners the burden of proving the truthfulness of any claims they make. The Commission defends Paragraph I,B as a "fencing in" provision justified by the petitioners' false representation that they had scientific evidence which formed a reasonable basis from which to conclude that substantially all X-11 users would lose significant amounts of weight.

Petitioners rely on *Federated Nationwide Wholesalers Service v. FTC*, 398 F.2d 253 (2d Cir. 1968), for the proposition that "in no event is the Commission warranted in decreeing what in effect is clearly a shifting of the burden of proof from itself to the petitioners." 398 F.2d at 260. There the challenged order prohibited the petitioners from representing themselves as wholesalers, but provided that "it shall be a defense in any enforcement proceeding under this order for [petitioners] to show" that they actually operated as wholesalers. 398 F.2d at 259. The court modified the order to prohibit petitioners from representing that they are wholesalers "unless they in fact" operate as wholesalers. 398 F.2d at 260. Paragraph I,B of the order before us resembles the modified order in *Federated Nationwide* more closely than the objectionable order in that case. Essentially, Paragraph I,B prohibits petitioners from making representations unless they are true; it does not make the truthfulness of the representation an affirmative defense petitioners must prove once the Commission establishes that petitioners have made representations. The burden of proof remains entirely on the Commission.

The authority of the Commission to impose "fencing in" restrictions is stated in *FTC v. Colgate-Palmolive Co.*, *supra*, 380 U.S. at 395,

> We think it reasonable for the Commission to frame its order broadly enough to prevent respondents from engaging in similarly illegal practices in future advertisements. As we said in *Federal Trade Comm'n v. Ruberoid Co.*, 343 U.S. 470, 473: "[T]he Commission is not limited to prohibiting the illegal practice in the precise form in which it is found to have existed in the past." Having been caught violating the Act, respondents "must expect some fencing in." *Federal Trade Comm'n v. National Lead Co.*, 352 U.S. 419, 431.

Although Paragraph I,B is as extreme a fencing in provision as we would sustain, we think it is justified in this case by the egregiousness of past representations and the propensity of the principal respondents to violate the Act.[13]

5. *Paragraph I,C.*

Paragraph I,C prohibits representing that any testimonial for a product "represents the typical or ordinary experience of members of the public who use the product unless this is the case." As we held in Part IV,B,1, *supra*, the advertisements did falsely and deceptively represent that the testimonials were indicative of the typical experience of X-11 users. This is a sufficient basis for Paragraph I,C.

Petitioners argue that the words "unless this is the case" shift the burden of proof but we think they do not. As we said of the words "unless they establish" in *Western Radio Corp. v. FTC*, 339 F.2d 937, 940 (7th Cir. 1964), *cert. denied*, 381 U.S. 938 (1965), "[w]e take this to mean no more than that petitioners must not speak falsely in advertising . . . ." Paragraph I,C is reasonably related to the unlawful practices and valid as issued.

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[13] Petitioners also assert the efficacy of methylcellulose, another ingredient of X-11, or the combination of PPA and methylcellulose, but petitioners have waived their right to appeal the ALJ's findings as to methylcellulose by not appealing them to the Commission. *See In Re Porter & Dietsch*, FTC Docket No. 9047, Dec. 20, 1977, at 15 n.17.

6. *Paragraph I,D.*

Paragraph I,D prohibits representations that a product contains "one or more unique ingredients or components, unless respondents can establish that any such ingredients or components are unavailable in products sold by others." Petitioners contend that Paragraph I,D is arbitrary in establishing only one definition for the word "unique." In Part IV,A,3, *supra*, we sustained the FTC's finding that "unique," in the context in which it was used, falsely represented to consumers that none of petitioners' competitors used PPA. This is a sufficient basis for Paragraph I,D.

Petitioners also argue that the words "unless [petitioners] can establish" improperly shifts the burden of proof, but *Western Radio* again controls. Paragraph I,D is reasonably related to the unlawful practices and is valid as issued.

7. *Paragraph I,E.*

Paragraph I,E requires petitioners to include in all advertisements the statements "DIETING IS REQUIRED" and "WARNING: THIS PRODUCT POSES A SERIOUS HEALTH RISK FOR SOME USERS. READ THE LABEL CAREFULLY BEFORE USING." Petitioners urge us to vacate this much of the order because it is unsupported by substantial evidence, creates an inconsistency in the treatment given to different persons engaged in the same conduct, and violates the First Amendment.[14]

Substantial evidence in the record as a whole supports the underlying findings on which these affirmative disclosures are based. In Part IV,A,1 and B,3, *supra*, we

[14] Petitioners do not appear to dispute the existence of FTC authority to require such disclosures. In *Warner-Lambert Co. v. FTC*, 562 F.2d 749, 756-762 (D.C. Cir. 1977), *cert. denied*, 435 U.S. 950 (1978), the court performed a detailed analysis and concluded that the Commission possessed the power to order "corrective advertising." We reached the same result in *National Commission on Egg Nutrition v. FTC*, *supra*, 570 F.2d at 164.

affirmed the Commission's findings concerning the necessity of a low calorie diet regimen,[15] and the health risk caused by PPA.

Petitioners' inconsistent treatment argument is premised upon the fact that the Commission did not impose a "DIETING IS REQUIRED" disclosure requirement on the manufacturer in *Carlay Co. v. FTC*, 153 F.2d 493 (7th Cir. 1946), and the Commission did not require the inclusion of either disclosure in *Alleghany Pharmacal*, *supra*. The *Carlay* case involved an entirely different product, which did not include PPA, and consequently comparison is not justified. In *Alleghany Pharmacal*, which did involve the same product, the advertisement quoted in the Commission's opinion made no representations concerning weight loss without dieting, the Commission found the advertisements contained no representations concerning safety, and the complaint apparently did not allege the failure to include the warning as an omission of material fact. In any event, when the safety of consumers is involved, as it is here, we would not preclude the Commission from imposing such a sanction simply because it failed to do so years before in another case.[16]

The fact that other firms in the market are not similarly burdened does not affect the validity of this order. "The purpose of Commission orders is not to put those employing deceptive acts or practices *in pari delicto* with each other." *Spiegel, Inc. v. FTC*, 494 F.2d 59, 64 (7th Cir.), *cert. denied*, 419 U.S. 896 (1974), quoting *Collier & Son Corp. v. FTC*, 427 F.2d 261, 276 (6th Cir. 1970).[17]

[15] Additionally, the record contained a letter from petitioner Furth to Petitioner Fraser, in which Furth wrote "Appedrine and Hungrex (even Odrinex) put emphasis on the tablets. That's murder, because the pills will not reduce weight one iota. It is the 'Plan' that will keep us out of hot water." As we have noted earlier, *see* note 4, *supra*, the "Plan" is no more than a suggested dietary regimen.

[16] *See* part III, *supra*.

[17] Petitioners rely on *Marco Sales Co. v. FTC*, 453 F.2d 1 (2d Cir. 1971), as support for the proposition that the inconsistent

(Footnote continued on following page)

The First Amendment permits the imposition of disclosure requirements in appropriate cases. *Virginia State Board of Pharmacy v. Virginia Citizens Consumer Council, supra,* 425 U.S. at 771-772 n.24; *Warner-Lambert Co. v. FTC, supra,* 562 F.2d at 758-759. We described the limitations placed on the scope of the authority to require disclosure in *National Commission on Egg Nutrition v. FTC, supra,* 570 F.2d at 164:

> The First Amendment does not permit a remedy broader than that necessary to prevent deception, or to correct the effects of past deception.

The "DIETING IS REQUIRED" disclosure is necessary to prevent deception. The record shows the X-11 tablets do not cause weight loss in the absence of a restricted calorie diet regimen. An advertisement that does not disclose this is deceptive. We therefore uphold the requirement that the phrase "DIETING IS REQUIRED" be included in future advertisements.

Unnecessarily broad, however, is the requirement that the advertising by Porter & Dietsch and Fraser of any product contain the words "WARNING: THIS PRODUCT POSES A SERIOUS HEALTH RISK FOR SOME USERS. READ THE LABEL CAREFULLY BEFORE USING." The Commission itself recognizes in its brief that this warning should not be required for products that do not contain PPA or similar compounds, because PPA is the only ingredient in X-11 shown by the record to cause a health risk. Yet the order is not so limited.

Moreover, the quoted words are not sufficiently specific even as to products to which they may

[17] *continued*
treatment requires us to vacate the order. *Marco Sales Co.,* however, is distinguishable from the case at bar. There the Commission issued an order against a manufacturer which was wholly inconsistent with an almost comtemporaneously issued Trade Regulation Rule without even adverting to the new regulation, much less explaining why it refused to adhere to that regulation. Agency adjudications do not create industry-wide standards as rulemaking does.

appropriately be applied. So far as the evidence shows, PPA is dangerous only to users who suffer from certain ailments.

The order is modified by making the warning requirement applicable only to products that contain PPA or similar compounds and changing it to read, "WARNING: THIS PRODUCT POSES A SERIOUS HEALTH RISK FOR USERS WITH HIGH BLOOD PRESSURE, HEART DISEASE, DIABETES, OR THYROID DISEASE. READ THE LABEL CAREFULLY BEFORE USING."

C. *Portions of the Order Applicable to Petitioners Kelly Ketting Furth and Joseph Furth.*

As we understand the position of the Furth petitioners, they join in the objections of Porter & Dietsch and William Fraser to Paragraph I, but make no arguments concerning the propriety of Paragraph II of the order, which requires them to cease and desist from disseminating advertisements for diet remedy or weight reduction products that in any way violate Paragraph I of the order. Petitioners have thus waived any objection to Paragraph II.[18] Fed. R. App. P. 28. Insofar as it applies to the Furth petitioners Paragraph II is valid as issued.

VII.

A. *Pay'n Save's Liability.*

Petitioner Pay'n Save asserts that it should have been neither prosecuted nor found liable. It contends that no possible public interest is served by prosecuting a retailer who had no part in the creation of the advertisements. Section 5(b) vests the Commission, not the court, with broad discretion in determining what

[18] Given the level of involvement of these petitioners indicated by the record, *see, e.g.,* note 15, *supra,* any such objections undoubtedly would have proven fruitless. *See, e.g., Carter Products, Inc. v. FTC,* 323 F.2d 523, 533-534 (5th Cir. 1963).

constitutes the public interest. *FTC v. Rhodes Pharmacal Co.*, 191 F.2d 744, 747 (7th Cir. 1951). As we have stated,

> [W]e have no authority to determine what is in the public interest, except negatively in the sense of insuring the Commission does not attempt to use its powers to vindicate private rights, and possibly in the case of *de minimis* activity.

Montgomery Ward & Co. v. FTC, 379 F.2d 666, 672 (7th Cir. 1967). The Commission has not sought to vindicate private rights here, and Pay'n Save's activity cannot be characterized as *de minimis*. Consequently Pay'n Save's public interest argument is without merit.

Pay'n Save also argues that it should not have been held liable for its use of advertisements prepared by the others in the absence of any knowledge of falsity. Nothing in the record indicates that Pay'n Save actually had knowledge of falsity. As to whether Pay'n Save should have known of the misrepresentations, the Commission concluded that "[i]f Pay'n Save had critically examined the advertising in light of the package insert, it should have been obvious that the advertising at least did not coincide with the plan." While this conclusion is undoubtedly correct, we need not rely on it in our discussion of liability because § 12[19] imposes a strict liability standard on disseminators of false advertising.

Section 12(a) states in relevant part:

> It shall be unlawful for any person, partnership, or corporation to disseminate, or cause to be disseminated, any false advertisement . . . .

The statute does not make mental state an element of violation and creates no exemption from liability for parties not involved in the creation of the false advertising or for unwitting disseminators of false

[19] The Commission held Pay'n Save liable for a violation of § 12, and, through § 12(b), of § 5. Pay'n Save was not held liable under § 5 directly, so we are concerned only with liability under § 12.

advertising. When Congress intended to make such an exemption it did so expressly. Section 14(a) makes certain violations of § 12 misdemeanors, but § 14(b) creates an exemption from criminal liability for advertising agencies and media under certain circumstances. 15 U.S.C. § 54. Under these circumstances the omission of any exemption from § 12 indicates that Congress did not intend one.

Pay'n Save relies on a series of decisions which it says indicates that the liability of an advertising agency may depend upon the extent of its participation in the deception, which in turn depends upon a knowledge of the falsity of the advertisements. *Colgate-Palmolive Co. v. FTC*, 310 F.2d 89, 92 (1st Cir. 1962); *Carter Products, Inc. v. FTC*, 323 F.2d 523, 533-534 (5th Cir. 1963); *Doherty, Clifford, Steers & Shenfield, Inc. v. FTC*, 392 F.2d 921, 927-929 (6th Cir. 1968). The Commission has, on occasion at least, exercised its enforcement discretion to dismiss complaints against advertising agencies that were merely acting under the direction and control of the advertiser. *See In re Bristol Myers Co.*, 46 F.T.C. 162, 176 (1949). Noting that this was a matter of administrative discretion, the First Circuit in the *Colgate-Palmolive* case enforced an order based on a finding that the agency was an "active . . . mover" in the deception, 310 F.2d at 92, but did not intimate that the FTC could not hold liable an agency that did not have knowledge of the deception. *Carter Products* is similar. There the Fifth Circuit enforced an order against an advertising agent that had "actually participated in the deception." 323 F.2d at 533-534. In *Doherty, Clifford* the Sixth Circuit did say that knowing participation in the deception was necessary but found it to exist. 392 F.2d at 928, 929. Thus in each of these cases the advertising agency knew of the falsity, and the court sustained liability. In none of them was the court required to decide whether the agency was liable in the absence of knowledge.

The court in *Doherty, Clifford* recognized that "the fact that an advertiser made its representations in good or bad faith is not determinative of whether such statements are deceptive and misleading." 392 F.2d at

Appendix A

925. It is settled that the advertiser's intent to deceive is not an element of the violation. *E.g., Chrysler Corp. v. FTC*, 561 F.2d 357, 363 n.5 (D.C. Cir. 1977); *Montgomery Ward & Co. v. FTC, supra*, 379 F.2d at 670. We find no basis in the language of § 12 for not applying these principles to an advertiser who is a retailer.

B. *The Propriety of the Remedy as to Pay'n Save.*

The extent of a party's culpability has an important bearing, however, on the nature of the relief that should be granted. Paragraph II of the Commission's order subjects both Pay'n Save and the Furth defendants, who did knowingly participate in the deception, to the same broad relief with respect to all diet remedies. They are prohibited from disseminating "any advertising which contains a representation or testimonial for such product prohibited by Paragraph I of the Order [which applies to Porter & Dietsch and Fraser], or which omits a disclosure for such product required by Paragraph I of this Order." We think the fact of Pay'n Save's uncritical participation in the X-11 co-operative advertising program is not sufficient to support an inference that there is a substantial danger that Pay'n Save's future advertising of diet remedies not manufactured or distributed by Porter & Dietsch will be deceptive. No need has been shown for "fencing in" Pay'n Save. This paragraph of the order, therefore, goes too far with respect to Pay'n Save and is modified to provide that, as to Pay'n Save, it applies only to advertising of Porter & Dietsch products.

ENFORCED AS MODIFIED.

A true Copy:

Teste:

Clerk of the United States Court of Appeals for the Seventh Circuit

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Appendix A

UNITED STATES COURT OF APPEALS

For the Seventh Circuit

Chicago, Illinois 60604

October 16, 1979.

Before

HON. WILBUR F. PELL, JR., Circuit Judge

HON. PHILIP W. TONE, Circuit Judge

HON. ALFRED Y. KIRKLAND, Senior District Judge*

PORTER & DIETSCH, INC., etc., et al.,

Petitioners,

vs.

FEDERAL TRADE COMMISSION,

Respondent.

Nos. 78-1324 and 78-1497

Petitions for Review of Orders of the Federal Trade Commission

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* Judge Alfred Y. Kirkland of the Northern District of Illinois sat on this case at the time of oral argument by designation. On May 1, 1979, Judge Kirkland became a senior district judge of the Northern District of Illinois and is continuing to sit on this case by redesignation.

Appendix A

ORDER ON REHEARING

Treating the "Petition of Pay'N Save Corporation for Rehearing In Banc" as a petition for rehearing and suggestion for rehearing in banc filed in the above-entitled cause, no judge in active service has requested a vote thereon, and all of the judges on the original panel have voted to deny a rehearing. Accordingly,

IT IS ORDERED that the aforesaid petition for rehearing be, and the same is hereby, DENIED.

The opinion is amended by inserting an asterisk following the letters "PPA" in the fifth line of text under heading II on page 5 of the slip opinion and adding the following footnote at the bottom of the page:

> After the issuance of this opinion the attention of the court was called to United States Trademark Registration No. 650,021 for "P.P.A." in International Class 5, former U.S. Class 18, filed by Alleghany Pharmacal Corporation. We used "PPA" as a convenient abbreviation without being aware of whether it had been used by others.

APPENDIX B — OFFICIAL REPORT OF ADMINISTRATIVE PROCEEDINGS, 90 F.T.C. 770, *ET SEQ.*

Complaint

IN THE MATTER OF

PORTER & DIETSCH, INC., ET AL.

ORDER, OPINION, ETC., IN REGARD TO ALLEGED VIOLATION OF THE FEDERAL TRADE COMMISSION ACT

Docket 9047. Complaint, July 29, 1975 — Final Order, Dec. 20, 1977

This order, among other things, requires a St. Paul, Minn. distributor of non-prescription drugs, its Chicago, Ill. advertising agency, and a Seattle, Wash. drug store chain to cease making unsubstantiated claims or misrepresenting that products contain a unique ingredient, or that users of weight control products can achieve weight loss without restricting their caloric intake or limiting their choice of foods. Further, the firms are required to include prescribed disclosure statements in promotional materials for products containing certain ingredients, and to recall all advertising data disseminated during the past two years for X-11 tablets.

Appearances

For the Commission: *Dean A. Fournier* and *William H. Patton.*
For the respondents: *Albert A. Carretta,* Washington, D.C. and *Jerold W. Dorfman,* New York City for Porter & Dietsch, Inc., et al. and *Michael Rayton,* Seattle, Washington for Pay'n Save Corporation.

COMPLAINT

The Federal Trade Commission, having reason to believe that Porter & Dietsch, Inc., a corporation, and William H. Fraser, individually and as an officer of said corporation, and Kelly Ketting Furth, Inc., a corporation, and Joseph Furth, individually and as an officer of said corporation, and Pay'n Save Corporation, a corporation, hereinafter sometimes referred to as respondents, have violated the provisions of the Federal Trade Commission Act, and it appearing to the Commission that a proceeding by it in respect thereof would be in the public interest, hereby issues this complaint stating its charges as follows:

PARAGRAPH 1. Respondent Porter & Dietsch, Inc. is a corporation organized, existing and doing business under and by virtue of the laws of the State of Minnesota, with its office and principal place of business located at 2453 University Ave., St. Paul, Minnesota. Respondent William H. Fraser is president of said corporation. He formulates, directs and controls the policies, acts and [2] practices of this corporate respondent, including the acts and practices hereinafter set forth. His address is the same as that of said corporation.

Appendix B

Complaint

Respondent Kelly Ketting Furth, Inc. is a corporation organized, existing and doing business under and by virtue of the laws of the State of Illinois, with its office and principal place of business located at 400 North Michigan Ave., Chicago, Illinois. Respondent Joseph Furth is an officer of said corporation and formulates, directs and controls certain acts and practices of this corporate respondent, including the acts and practices hereinafter set forth. His address is the same as that of said corporation.

Respondent Pay'n Save Corporation is a corporation organized, existing and doing business under and by virtue of the laws of the State of Washington, with its office and principal place of business located at 1511 Sixth Ave., Seattle, Washington.

PAR. 2. For purposes of this complaint, the term "commerce" shall mean commerce as defined in the Federal Trade Commission Act.

PAR. 3. Respondents Porter & Dietsch, Inc. and William H. Fraser are now and have been engaged in the packaging, advertising, offering for sale and sale of various products at wholesale and retail levels. Among such products is a non-prescription preparation which comes within the classification of "drug" (as that term is defined in the Federal Trade Commission Act) and which has the following designation, directions for use and active ingredients:

Designation: "X-11 Tablets"

Dosage:

One tablet three times daily, one-half hour before each meal.

Active Ingredients:

Vitamin A	1388.0 U.S.P. units
Vitamin B	0.5 mg.
Vitamin B_2	0.5 mg.
Vitamin B_6	1.0 mg.
Vitamin C	15.0 mg.
Calcium Pantothenate	1.0 mg.
[3]Niacinamide	5.0 mg.
Vitamin E	5.0 int. units
Vitamin B_{12}	0.5 mg.
Phenylpropanolamine Hydrochloride	25.0 mg.
Methylcellulose	25.0 mg.
Caffeine	25.0 mg.

Appendix B

Complaint

PAR. 4. Respondent Kelly Ketting Furth, Inc. is now and has been the advertising agency of Porter & Dietsch, Inc. Respondent Joseph Furth is now and has been the account executive in such agency responsible for advertising of products marketed by Porter & Dietsch, Inc. As such, these respondents have prepared and placed for publication advertising material, including but not limited to the advertising referred to herein, to promote the sale of the aforesaid preparation and other products. In the course and conduct of their business, and at all times mentioned herein, these respondents have been and are now in substantial competition, in or affecting commerce, with other corporations, firms and individuals in the advertising business.

PAR. 5. Respondent Pay'n Save Corporation operates a chain of drug and sundries stores in Washington, Oregon, Alaska, California, Hawaii, and Canada. Said respondent is now and has been engaged in the advertising, offering for sale and sale of various products including the aforesaid preparation.

PAR. 6. In the course and conduct of their business, respondents Porter & Dietsch, Inc. and William H. Fraser ship, distribute and cause to be shipped and distributed the aforesaid preparation from their place of business in the State of Minnesota to retail stores and purchasers located in various other States of the United States.

In the course and conduct of its business, respondent Pay'n Save Corporation operates retail stores and storage warehouses in several States of the United States. Said respondent causes the aforesaid preparation to be shipped from Minnesota to storage points and Pay'n Save stores located in various other states, for sale to the general public.

In the further course and conduct of their businesses, and using means and mechanisms of commerce, these respondents and respondents Kelly Ketting Furth, Inc. and Joseph Furth cause advertisements for said preparation to be published in media of interstate circulation. [4]

Respondents maintain, and at all times mentioned herein have maintained, a substantial course of trade in the aforesaid preparation and advertisements, in or affecting commerce.

PAR. 7. In the course and conduct of their businesses, respondents have disseminated, and caused the dissemination of, certain advertisements concerning said preparation by the United States mail and by various means in or having an effect upon commerce, including but not limited to advertisements inserted in newspapers, for the purpose of inducing and which were likely to induce, directly or indirectly, the purchase of said preparation; and have disseminated

and caused the dissemination of advertisements concerning said preparation by various means, including but not limited to the aforesaid media, for the purpose of inducing and which were likely to induce, directly or indirectly, the purchase of said preparation in or having an effect upon commerce.

PAR. 8. Typical of the statements and representations in said advertisements, but not all inclusive thereof, are the following:

Eat well . . . and lose that fat! - without ever missing a meal . . .

• • • • • • •

You eat 3 satisfying balanced meals a day - plus snacks. You eat what you want . . .

• • • • • • •

You do not deny yourself.

• • • • • • •

. . . Laboratory Science has perfected a Tiny Tablet for EASY REDUCING . . . clinic-tested ingredients . . .

• • • • • • •

I lost 80 pounds! When I started on the X-11 Reducing Plan, I weighed 205 pounds. Now my weight is down to 125 pounds. I enjoy wearing dresses sizes 11 or 12's, rather than size 20 1/2 . . .

• • • • • • •

Part of the secret of this method is a unique ingredient . . . which puts a "brake" on your cravings for sweets, candy, pastries, rich gravies.

[6] PAR. 9. Through the use of said advertisements and others similar thereto but not specifically set out herein, respondents have represented and are now representing, directly or by implication, that:

A. Users of X-11 tablets can lose weight without restricting their accustomed caloric intake and while they continue to eat the foods of their choice.

B. Respondents have a reasonable basis from which to conclude that substantially all users of X-11 tablets will lose a significant amount of weight.

C. The X-11 tablet contains a unique ingredient.

PAR. 10. In truth and in fact:

A. Users of X-11 tablets cannot lose weight without restricting their accustomed caloric intake nor while they continue to eat the foods of their choice. In fact, each X-11 package includes a diet highly restricted as to calories and choice of foods, which must be adhered to if weight loss is to be achieved.

B. Respondents have no reasonable basis from which to conclude that substantially all users of X-11 tablets will lose a significant amount of weight.

C. The X-11 tablet does not contain any unique ingredient.

PAR. 11. Several of the advertisements described and alluded to in Paragraph Eight hereof include testimonials reciting weight reduction and other figure improvements purportedly attained by lay users of the aforesaid preparation, when such stated results do not reflect the typical or ordinary experience of consumers with said preparation under circumstances similar to those depicted in the advertisements. These advertisements do not disclose or identify such typical or ordinary experience in any way. Thus, respondents have failed to disclose in their advertising a material fact which, if known to consumers, would be likely to affect their consideration of whether or not to purchase said preparation. [7]

PAR. 12. Respondents have marketed and advertised X-11 tablets without disclosing in the advertising thereof that persons with high blood pressure, heart disease, diabetes or thyroid disease should use said preparation only as directed by a physician. Inasmuch as a substantial number of overweight persons are suffering from one or more of said physical conditions, respondents have failed to disclose in their advertising a material fact which, if known to such persons, would be likely to affect their consideration of whether or not to purchase said preparation.

PAR. 13. Respondents have marketed and advertised the "X-11 Reducing Plan" without disclosing in the advertising thereof that a highly restricted caloric diet is an integral part of said plan. Such fact, if known to consumers, would be likely to affect their consideration of whether or not to purchase said product. Thus, respondents have failed to disclose a material fact in their advertising.

PAR. 14. The advertisements referred to in Paragraphs Eight, Eleven, Twelve and Thirteen were and are misleading in material respects, as alleged in Paragraphs Ten, Eleven, Twelve and Thirteen, and constituted, and now constitute, "false advertisements," as that term is defined in the Federal Trade Commission Act, and the statements, representations and omissions described in Paragraphs Nine, Eleven, Twelve and Thirteen were and are misleading, deceptive and unfair acts or practices.

PAR. 15. The use by respondents of the aforesaid misleading, deceptive and unfair statements, representations, acts and practices, and the dissemination of the aforesaid "false advertisements," have had and now have the capacity and tendency to mislead members of the consuming public into the erroneous and mistaken belief that said statements and representations were and are true and complete, and into the purchase of substantial quantities of X-11 tablets by reason of said erroneous and mistaken belief.

PAR. 16. In the course and conduct of their businesses, and at all times mentioned herein, respondents Porter & Dietsch, Inc., William H. Fraser and Pay'n Save Corporation have been and now are in substantial competition, in or affecting commerce, with corporations, firms and individuals in the sale of products and services for weight reduction. [8]

PAR. 17. The aforesaid acts and practices of respondents including the dissemination of "false advertisements," as herein alleged, were and are all to the prejudice and injury of the public and of respondents' competitors and constituted, and now constitute, unfair and deceptive acts and practices in commerce and unfair methods of competition in or affecting commerce in violation of Sections 5 and 12 of the Federal Trade Commission Act.

Commissioner Thompson dissenting.

DISSENTING STATEMENT OF COMMISSIONER MAYO J. THOMPSON

JULY 29, 1975

I share the majority's view that the principal distributor of an alleged weight-reducing pill ought to be able to substantiate the claims he makes for it and that, if it is in fact dangerous for people with heart disease, diabetes, high blood pressure, and other diseases

to take it, he ought to say so in his ads. But I cannot agree with my Brethren that a *retailer* with no involvement in the preparation of the ads in question should be subjected to liability here.

The advertisements in question are prepared by the distributor of these pills, Porter & Dietsch,[1] with the actual copy being written by its president and controlling owner, Mr. William H. Fraser. Advertising mats are prepared and sent out to the major regional and local drug chains, including Pay'n Save Corporation, a Seattle-based drug retailer with some 90 stores located in five (5) states. The distributor pays for approximately 90 percent of the cost of these ads, with the cooperating retailer paying the remaining 10 percent. Since the messages are directed to the ultimate consumer and generally exhort him to buy from the drug chain, it is the latter's name rather than that of the distributor which appears in the ads.

Why pick on Pay'n Save? Other drug chains have been similarly "involved," including Fred Meyer (Portland); Western Drug (Montana); Pay Less (Tacoma); Skaggs and Grand Central Stores (Boise); Tiffany [2] Drugstores (Eugene Oregon); Drug Fair (Washington, D.C.); and Walgreens (Chicago). The staff explains the selection of Pay'n Save by simply noting that it is the largest of the participating chains in the Pacific Northwest. (The investigation was conducted by our Seattle regional office.) In other words, Pay'n Save was the most *convenient* retailer target.

It is conceded that Pay'n Save "had a significantly lower level of involvement" in the ads than Porter & Dietsch and its president, Mr. Fraser, but the staff believes this factor is more than outweighed by the need to establish a new legal precedent. An "important aspect of this case," the staff tells us, "is the inclusion of the advertising retailer, Pay'n Save Corporation, as a named respondent." A retailer who *uses* a deceptive ad, we're told, ought to be held just as liable as the fellow who created it in the first place. Had Pay'n Save made a "thoughtful" examination of the packages in question, including the disclosures on the package insert, it would have known something was wrong.

The problem, the staff reports to us, is that the country's retailers have been getting away with murder in this area. While "major general-merchandise retailers are frequently involved and/or specifically identified as the advertiser in highly questionable ads devoted to a single product, our research has disclosed no clearcut instances of such retailers being held responsible for manifestly deceptive product claims appearing in such ads. Subjection of Pay'n Save to

[1] Porter & Dietsch is the "exclusive national distributor" of this product, the "X-11" reducing pill.

the 'cease and desist' provisions of this order will help to reestablish this responsibility principle in the context of this type of advertising."

So there we have it. The staff wants to establish a new principle of trade regulation law. *Any retailer who runs an ad prepared by a supplier is legally liable for the truthfulness of everything in it.* Never mind that he didn't participate in the preparation of the ad and that it would be economically prohibitive for [3] him to maintain a staff of scientists and lawyers to screen all the supplier ads that a substantial retailer is confronted with in the course of a business year. In short, strict "no-fault" liability. Run the ad at your peril.

I think the Commission is embarking on an unwise, dangerous, and unnecessary course of action here. It is unwise because it defies common sense. It is dangerous because it imposes an intolerable cost burden on the nation's retailers that can only be passed on to the consumer in the form of still more inflated prices than those we now labor under. And it is unnecessary because a cease and desist order that stops the development of deceptive advertisements at the headwaters clearly makes it unnecessary to seine all the downstream tributaries.

I would dismiss Pay'n Save from this complaint.

Initial Decision by Daniel H. Hanscom, Administrative Law Judge

May 21, 1976

I

Statement of the Case

ALLEGATIONS OF COMPLAINT

The complaint in this proceeding charged respondents Porter & Dietsch, Inc., William H. Fraser, Kelly Ketting Furth, Inc., Joseph Furth and Pay'n Save Corporation with the dissemination of false advertisements and unfair, misleading and deceptive statements and representations in the advertising, promotion and sale of X-11 tablets in violation of Sections 5 and 12 of the Federal Trade Commission Act.[1] More specifically, the complaint alleged that respondents disseminated advertisements which misrepresented,

[1] Then Commissioner Thompson dissented from the naming of Pay'n Save Corporation, a large West Coast drug chain, as a respondent in this proceeding on the grounds, *inter alia*, that he could not agree that "a *retailer* with no involvement in the preparation of the ads in question should be subjected to liability here," and that Pay'n Save was being singled out among many drug store chains, as "the most *convenient* retailer target." See statement issued with the complaint.

directly or by implication, that "[u]sers of X-11 tablets can lose weight without restricting their accustomed caloric intake and while they continue to eat the foods of their choice," that respondents had a "reasonable basis from which to conclude that substantially all users of X-11 tablets will lose a significant amount of weight," and that each "X-11 tablet contains a unique ingredient."

The complaint further alleged that some of respondents' advertisements included testimonials reciting weight reduction and other figure improvements purportedly attained by lay users of the "aforesaid preparation" which did not reflect the "typical" or "ordinary" experience of consumers "under circumstances [3] similar to those depicted in the advertisements." Failure of the advertisements to disclose or identify the typical or ordinary experience of persons using the tablets was alleged to constitute a failure to disclose a material fact which, if known, would have affected the consumer's consideration of "whether or not to purchase said preparation."

The complaint also alleged that respondents "marketed and advertised X-11 tablets without disclosing in the advertising thereof that persons with high blood pressure, heart disease, diabetes or thyroid disease should use [them] only as directed by a physician," and that in doing so respondents failed to disclose a material fact in such advertising. Finally, the complaint charged that the "X-11 Reducing Plan" was marketed and advertised without disclosing that "a highly restricted caloric diet [was] an integral part of said plan," and that such constituted a failure to disclose a material fact.

RESPONDENTS' ANSWERS

Respondents filed answers denying most of the substantive allegations of the complaint, and raising a number of affirmative defenses. Respondents Porter & Dietsch, Inc., William H. Fraser, Kelly Ketting Furth, Inc., and Joseph Furth denied that they ever marketed a product designated "X-11 Tablets," contending that they were engaged in the sale of the "X-11 Reducing Plan" which "includes for ingestion tablets having the ingredients set forth in Paragraph Three of the Complaint." The foregoing respondents also denied representing that "users of X-11 tablets can lose weight without restricting their accustomed caloric intake and while they continue to eat the foods of their choice," and denied representing "that substantially all users of X-11 tablets [would] lose a significant amount of weight." Respondents contended that they had advertised [4] only the "X-11 Reducing Plan," not tablets and represented only that users of the "X-11 Reducing Plan" would lose some weight, and

that they had a reasonable basis for this assertion. Lack of public interest also was urged.

Respondent Pay'n Save maintained that it received the prepared X-11 advertisements from Porter & Dietsch, Inc., and therefore "cannot be held liable for the truthfulness of representations made therein by others."

Prior to the completion of evidentiary hearings respondents Porter & Dietsch, Inc., William H. Fraser, Kelly Ketting Furth, Inc. and Joseph Furth filed an amended answer contending that the Federal Trade Commission is "precluded from bringing this proceeding . . . under the principles of collateral estoppel and/or stare decisis." Respondent Pay'n Save likewise filed an amended answer contending that "Complaint Counsel is precluded from bringing this proceeding under the principles of res judicata, collateral estoppel and/or stare decisis." According to respondents, three litigated decisions, *Alleghany Pharmacal Corporation*, 75 F.T.C. 990 (1969), *Hanover House* and *Romar Sales*, proceedings before the Postal Service,[2] preclude trial in this proceeding of issues relating to the "safety and efficacy of phenylpropanolamine as an appetite suppressant for weight reduction."

PROCEDURAL HISTORY

Complaint was served on the various respondents between the end of August and early September 1975. On September 10, the law judge issued an order directing counsel to attempt agreement on a timetable for completion of prehearing matters and a date and place for hearings on the merits. Thereafter, at the request of counsel for Porter & Dietsch, Inc., William H. Fraser, Kelly Ketting Furth, Inc., and Joseph Furth, a prehearing conference was held on October 7, 1975, [5] and a timetable was issued the following day setting hearings on the merits to commence January 6, 1976.

The parties disagreed as to the location of hearings. After considering all submissions, the law judge ordered that hearings be held in Seattle, Washington, where Pay'n Save Corporation and its counsel[3] and a number of witnesses and complaint counsel were located, and in Washington, D.C., to take the testimony of East Coast witnesses. Hearings in Chicago, Illinois, to accomodate Porter &

[2] *Hanover House* and *Romar Sales Corp.*, P.S. Dkt. Nos. 2/143 and 2/144, decision of December 5, 1973.

[3] Original counsel for Pay'n Save Corporation withdrew on October 2, and Albert A. Carretta, counsel for Porter & Dietsch, Inc., William H. Fraser, Kelly Ketting Furth, Inc., and Joseph Furth, took over as counsel for all respondents. However, on October 28, Mr. Carretta withdrew as counsel for Pay'n Save Corporation because of a possible conflict of interest between that respondent and one or more of the other respondents. Original counsel for Pay'n Save Corporation then reentered the proceeding.

Dietsch, Inc., William H. Fraser, Kelly Ketting Furth and Joseph Furth were also offered if requested by those respondents.[4]

In the meantime, Porter & Dietsch, Inc., William H. Fraser, Kelly Ketting Furth, Inc., and Joseph Furth moved on September 24, 1975, for a "Corrective News Release" and a stay of the date for filing an answer on the ground that the Commission's News Release failed to contain the usual caveat that the Commission issues a complaint when it has "reason to believe" that the law has been violated, and that such action did not imply adjudication of the matters alleged. This motion for a "Corrective News Release" was certified to the Commission recommending that it be granted, but the request for a stay of the date for filing an answer was denied. On October 17, 1975, the Commission granted the motion for such correction. [6]

Thereafter, discovery and various other pretrial proceedings continued. The law judge issued a number of subpoenas requiring the production of documents and information by respondents, directed the production of specified Commission materials, ordered the taking of certain depositions and disposed of a variety of motions. Included among the latter were a motion and supporting memorandum of Porter & Dietsch, Inc., William H. Fraser, Kelly Ketting Furth, Inc., and Joseph Furth to "Dismiss Complaint Before Trial For Lack Of Public Interest Sufficient To Justify Issuance Of A Cease And Desist Order" and their motion and supporting memorandum for a "Supplementary Corrective News Release." The latter motion was certified to the Commission with a recommendation pursuant to §3.22 of the rules and was denied by the Commission on December 19, 1975.

Respondent Pay'n Save Corporation also filed a motion to "Dismiss Complaint Before Trial Or, In The Alternative, For Summary Decision" which was supported by a memorandum filed by Porter & Dietsch, Inc., William H. Fraser, Kelly Ketting Furth, Inc., and Joseph Furth. This motion was denied by the law judge on December 30, 1976.

On December 23, 1975, all respondents filed an action in the U.S. District Court for the District of Columbia seeking a declaratory judgment and restraint of further proceedings in this matter. They alleged that a cease and desist order against them would not be in the public interest, that the Commission's News Releases were improper, and that the scheduling of hearings in Seattle and Washington, D.C., rather than in one location "convenient to all parties," violated the due process clause of the Fifth Amendment,

[4] On December 29, 1975, counsel for respondents formally declined hearings in Chicago, Illinois, and evidentiary hearings were not held at this location.

the Administrative Procedure Act and the Commission's rules. On January 5, 1976, after hearing oral argument, the District Court denied respondents' motion for a preliminary injunction and thereafter dismissed the complaint. [7]

Hearings on the merits commenced in Seattle, Washington, on January 7 and concluded in Washington, D.C., on January 26, 1976, 8 actual hearing days having been utilized during that period. The record consisting of 220 exhibits, many of them multi-paged, and 1,405 pages of transcript was closed by order of the law judge on February 10. Twelve witnesses testified including the individual respondents and an official of Pay'n Save Corporation, and the testimony of three witnesses was entered in the record by stipulation. Complaint counsel called four medical or scientific experts, Drs. Margen, Drenick, Prout and Sorer, and respondents Porter & Dietsch, Inc., William H. Fraser, Kelly Ketting Furth, Inc., and Joseph Furth called three, Dr. Fineberg, a medical doctor, Dr. Silverman, a pharmacologist, and Dr. Hoebel, a specialist in physiological psychology.

At the conclusion of the case-in-chief respondents orally moved to dismiss on the ground that complaint counsel had not made out a prima facie case (Tr. 1038-97). Ruling was deferred by the law judge until decision on the entire case after all evidence had been received, and permission was granted to respondents to reduce their motion to writing supporting it with record references and legal authority. On March 29, 1976, respondents (except Pay'n Save) filed a comprehensive written motion to dismiss with a separately bound appendix in support. This motion will be referred to hereinafter as "Motion to Dismiss" and will be ruled upon in this Initial Decision in accordance with the findings, discussion and conclusions set forth.

This matter is now before the undersigned for decision based upon the allegations of the complaint, the answers, the evidence and the proposed findings of fact, conclusions and legal authority filed by all parties. All proposed findings of fact, conclusions and arguments, including those in the Motion to Dismiss, not specifically found or accepted herein, are rejected. The law judge, having considered the entire record, and all the contentions of the parties, makes the following findings and conclusions and issues the order set out at the end hereof: [8]

II

FINDINGS OF FACT

RESPONDENTS

1. Respondent Porter & Dietsch, Inc. (Porter & Dietsch), is a Minnesota corporation with its office and principal place of business in St. Paul. It is engaged in the packaging and sale of pharmaceutical products, principally by mail and through retail drug stores (Ans. P&D, ¶1; Fraser, Tr. 753-54). Porter & Dietsch has sold its X-11 tablets since 1967 (Ans. P&D, ¶3; Fraser, Tr. 769, 823) and, although a few other products are sold, the tablets are by far its largest volume item, amounting to over 80 percent of all sales (Fraser, Tr. 757-61).

2. Individual respondent William H. Fraser is the president and sole owner of Porter & Dietsch (Fraser, Tr. 753-54). As such, Mr. Fraser formulates, directs and controls the policies, acts and practices of corporate respondent Porter & Dietsch (Ans. P&D, ¶1).

3. In the course and conduct of their business, Porter & Dietsch and William H. Fraser have been and now are in substantial competition in or affecting commerce (as "commerce" is defined in the Federal Trade Commission Act) with other corporations, firms and individuals in the sale of products and services for weight reduction (Ans. P&D, ¶16).

4. Respondent Kelly Ketting Furth, Inc. (Kelly Ketting Furth) is an advertising agency incorporated in Illinois, with its office and principal place of business in Chicago (Ans. P&D, ¶1). Since its organization in 1968, Kelly Ketting Furth has been, and is, the advertising agency for Porter & Dietsch in the marketing of X-11 tablets (Ans. P&D, ¶4; Fraser, Tr. 805; Furth, Tr. 927-32). [9]

5. Individual respondent Joseph Furth is a vice-president of Kelly Ketting Furth and is the advertising account executive for respondent Porter & Dietsch (Ans. P&D, ¶4; Furth, Tr. 927-36). Mr. Furth participates in the management of Kelly Ketting Furth and is among those responsible for the formulation, direction and control of its acts and practices, including those alleged in the complaint (Ans. P&D, ¶1).

6. In the course and conduct of their business Kelly Ketting Furth and Joseph Furth are now, and have been, throughout the period that Kelly Ketting Furth has been the advertising agency for Porter & Dietsch, in substantial competition in or affecting commerce (as "commerce" is defined in the Federal Trade Commission Act) with

other corporations, firms and individuals in the advertising business (Ans. P&D, ¶4).

7. Pay'n Save Corporation is a Washington corporation with its headquarters located in Seattle. It is a major chain of retail drug and sundry stores with outlets located principally in the Northwest and in northern California with some stores in Alaska and Hawaii (Ans. P&D, ¶¶ 1 and 5). Gross sales volume for the 12-month period ending November 1, 1975, was approximately $290,000,000 (Stipulation. Tr. 435). Porter & Dietsch's X-11 tablets have been sold by Pay'n Save since 1969 (Ans. P&D, ¶5; Palmer, Tr. 507-08).

8. In the course and conduct of its business and throughout the period of its marketing and/or advertising of Porter & Dietsch's X-11 tablets, Pay'n Save has been and now is in substantial competition in or affecting commerce (as "commerce" is defined in the Federal Trade Commission Act) with other corporations, firms or individuals in the sale of various products, including products sold as aids in weight reduction (Ans. P&S, ¶¶ 2, 4, 5). [10]

X-11 TABLETS

1. *Nature and sales*

9. Porter & Dietsch purchase the X-11 tablets they market from the manufacturer in polyethylene pouches containing 21 tablets each. These pouches are then packaged in cartons of two sizes - one box containing two (2) pouches totaling 42 tablets and a larger size containing five (5) pouches totaling 105 tablets (Fraser, Tr. 769-70). The smaller box is normally sold at retail for $3.00 and the larger size for $5.00 (Adm. P&D, No. 9b; CX 36, 39, and 62). In addition to the tablets, each box contains a leaflet providing directions for the purchaser in using the tablets and some advice about obesity, a rudimentary low-calorie diet for a 5-week period, a "calorie value chart" for a limited number of foods, a weight chart and a "warning" against use by individuals with certain physical conditions unless medically supervised (CX 37 and 40). The outside of the box containing the X-11 tablets features in bold lettering "X-11 Reducing Plan" and the headline "EAT WELL!! — and LOSE THAT FAT" (CX 36, 38, 39 and 41). The ingredients, the "adult dose," and a "Caution" (warning) are also provided.

10. X-11 tablets were, and are, advertised and marketed extensively throughout the United States as a reducing aid or preparation for the obese, and for those who wish to shed what they consider to be excess body weight. Approximately 80 percent of all retail chain stores in the nation sell X-11 tablets (Fraser, Tr. 783), and annual

sales for the year ending April 30, 1975, were in the area of $1,789,000 (Fraser, Tr. 759-61). Each X-11 tablet contains 25 milligrams of phenylpropanolamine, 25 milligrams each of methylcellulose and caffeine and vitamins A (1388 U S P units), B_1 (0.5 mg), B_2 (0.5 mg), B_6 (1 mg), C (15 mg), calcium pantothenate (1 mg), niacinamide (5 mg), E (5 int. units), and B_{12} (0.5 mcg) (Ans. P&D, ¶3). The ingredients in the X-11 tablets allegedly conducive to weight loss are phenylpropanolamine and methylcellulose. The former is an [11] amphetamine-related compound, which is claimed to act as an appetite suppressant. The characteristics of phenylpropanolamine will be considered in subsequent findings dealing with the representations contained in respondents' advertising. Methylcellulose is also represented in the marketing of X-11 tablets as an aid to weight loss, and the characteristics of this substance will also be considered.

11. The promotional approach of respondents with respect to phenylpropanolamine and methylcellulose in marketing X-11 tablets is illustrated by statements in an advertisement given wide circulation in *TV Guide* for October 18 through 24, 1975, which stated under a picture of two fingers holding a pill adjacent to the headline "WHAT EACH TABLET CONTAINS" (CX 13):

> 25mg METHYLCELLULOSE A pure vegetable extract which expands and is intended to give one a feeling of being fuller.
>
> 25mg PHENYLPROPANALOMINE [sic] An appetite depressant intended to help give one the feeling of a restricted appetite.

(See also CX 69-73 and 90-91.) Other advertisements hold out the effects purportedly attributable to methylcellulose and phenylpropanolamine, i.e., a feeling of fullness and depressed appetite, without specifically identifying these substances (CX 4-8, 10, 14-15, 43, 46-47, 50, 52-56, 59, 61, 63-64, 67-68, 74, 77-80, 82-85 and 87-88).

2. *Respondents were engaged in the advertising and sale of diet tablets*

12. Respondents place great emphasis on their contention that they neither marketed nor advertised "tablets" but, rather, a "plan." Insofar as this [12] contention involves a defense that representations were not made to the public in respondents' advertisements as to the characteristics and qualities of the X-11 tablets, and the weight losses achievable from their use, it is contrary to the evidence and is rejected. Respondents' advertisements, directly and by implication, conveyed the net impression to the public that a

"wonder" preparation for easy weight reduction - the X-11 tablets - was available. The advertisement in the *Seattle Times* September 10, 1972, reprinted herein, is illustrative (CX 18). This advertisement begins with the banner headline "X-11 IS HERE!" and then tells readers who are overweight and want to reduce that they can "EAT WELL. . .AND LOSE THAT FAT! - without ever missing a meal." Weight losses of 5, 10, 25 or more pounds are represented, "GET RID OF 5, 10, 25 OR MORE POUNDS!," as achievable with X-11 tablets. A picture of an attractive and trim lady is given prominence who is quoted as saying "I LOST 80 LBS!" The advertisement announces to the overweight reader that you "satisfy your appetite while you take off pounds and inches" without "strenuous exercises" and "without starvation dieting hunger," that "[Y]ou do not deny yourself," and that "you lose weight. . .while you eat well." How is all this accomplished? The advertisement answers: "here's why" — a *tablet* which:

1. COUNTERACTS HUNGER

Take one of these tablets a half-hour or so before your regular meals. It combines a pure vegetable extract that has no calories, and quickly starts acting to provide the feeling of a fuller, satisfied, contented stomach. You eat 3 satisfying balanced meals a day - plus snacks. You eat what you want, but eat less because you don't feel so hungry throughout the day.


X-11 IS HERE!
eat well ...and lose that Fat!
GET RID OF 5, 10, 25 or MORE POUNDS!
COUNTERACTS HUNGER
FORTIFIED WITH VITAMINS
"I LOST 80 LBS!"
SATISFACTION GUARANTEED OR MONEY BACK
HURRY IN FOR THE X-11 REDUCING PLAN OR MAIL COUPON
X-11
42 Tablets—$3.00
105 Tablets-$5.00
PAY 'n SAVE
AVAILABLE AT ALL STORES


GUARANTEED or MONEY BACK
If Your Drug or Department Store has run out of stock
FOR QUICK ACTION USE THIS COUPON TO ORDER BY MAIL
MAIL-SUPPLY
Chicago Tribune
EAT WELL...and Get Rid of 5, 10, 25 or More Pounds!
Eat 3 Sensible Meals a Day —and SLIM DOWN!
MONEY BACK GUARANTEE
with This Amazingly Easy Reducing Plan!

[15] 2. ACTS AS AN APPETITE APPEASER

Part of the secret of this method is a unique ingredient that acts as a beneficial appetite appeaser, which puts a "brake" on your cravings for sweets, candy, pastries, rich gravies. High-Fat/High-Calorie foods - everything. It helps you conduct a kind of psychological warfare with yourself as you break some bad old eating habits you probably thought you were stuck with forever. Thus, your appetite is appeased while you take off fat.

13. The advertisement appearing in the *Seattle Times*, July 8, 1973, also reprinted, emphasizes testimonials of ladies reporting very substantial weight losses (CX 19). It also contains a picture of two fingers holding the X-11 tablet, and advises the reader that if not 100 percent delighted, the "first package" of either 42 tablets or 105 tablets may be returned for an immediate refund.

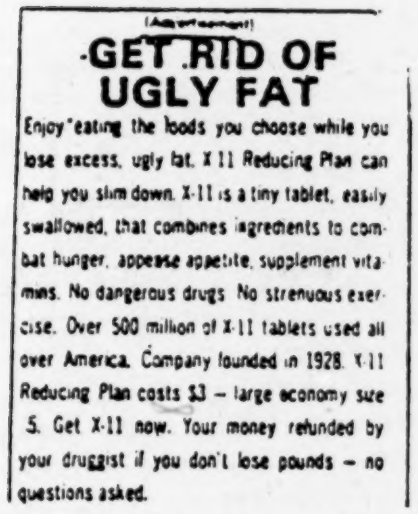
14. The advertisement in *The Idaho Statesman*, September 9, 1973, likewise reprinted, contains two pictures of the X-11 tablet (CX 48). The first features the picture of a young lady holding up an X-11 tablet and states:

> NOW. . . LABORATORY SCIENCE HAS PERFECTED A TINY PRE-MEAL TABLET WITH A PLAN THAT LETS YOU ENJOY FOODS YOU CHOOSE

The bottom half of this advertisement emphasizes the X-11 tablet by a much larger picture of two fingers holding the tablet with adjacent paragraphs entitled "COUNTERACTS HUNGER," "ACTS AS APPETITE APPEASER," containing the same text referred to in Finding 12, and "FORTIFIED WITH VITAMINS, MINERALS." The advertisement concludes by announcing "42 Tablets 2.98," "105 Tablets 4.98." [19]

15. The elaborate advertising supplement distributed in the *Chicago-Tribune*, February 11, 1973, although varying in language, is similar in its message and representations to the foregoing advertisements (CX 49). A post card for mailing to the Walgreen drug chain is printed within the advertisement with the admonition to prospective purchasers: "IF YOUR STORE HAS RUN OUT OF X-11 TABLETS HURRY!!!" "FILL OUT AND MAIL THIS COUPON FOR YOUR SUPPLY." This advertisement is headlined "X-11 IS HERE" and gives prominence to the picture of a tablet being held between two fingers, telling Chicago-area readers that ". . . Laboratory Science has perfected a Tiny Tablet for EASY REDUCING."

16. Some of respondents' smaller advertisements designed for insertion in newspaper columns, or in fractions of pages in periodicals, condense the representations contained in the larger advertisements and refer to X-11 simply as a "tiny tablet." The following is an example (CX 42):



GET RID OF UGLY FAT

Enjoy eating the foods you choose while you lose excess, ugly fat. X-11 Reducing Plan can help you slim down. X-11 is a tiny tablet, easily swallowed, that combines ingredients to combat hunger, appease appetite, supplement vitamins. No dangerous drugs. No strenuous exercise. Over 500 million of X-11 tablets used all over America. Company founded in 1928. X-11 Reducing Plan costs $3 – large economy size 5. Get X-11 now. Your money refunded by your druggist if you don't lose pounds – no questions asked.

(See also CX 5-7 and 77.)

[20] 17. Other advertisements told members of the public that they could "LOSE THAT FAT" but "EAT SUFFICIENTLY" by taking "a pre-meal X-11 Tablet before meals" (CX 51) and that "today" there is "an amazing new reducing plan with X-11 Tablets" (CX 52, 61 and 84). Still other advertisements were again specific in telling the public "WHAT EACH TABLET CONTAINS" (CX 13, 69-73, 90 and 91). Occasional advertisements stated "NO PRESCRIPTION NEEDED" (CX 12, 57 and 65), and some told the public to "[A]sk the pharmacist for a 42 tablet pack of X-11 Reducing Aid" (CX 53 and 66).

18. With few exceptions, respondents' advertisements concluded with a coupon or statement offering *tablets* to the public, usually 42 for $3.00 and 105 for $5.00 (see *e.g.*, CX 18-19 and 49 reprinted in this decision).

19. The ladies whose testimonials are prominently displayed in the *Seattle Times* advertisement (CX 19), and published in other newspapers (CX 1, 16, and 76), perceived the advertisements as promoting pills or tablets. Mrs. George Stowe in her initial letter to Porter & Dietsch refers to taking "X-11 tablets" (CX 149). Mrs. Beverly Tellier begins by stating "I am a user of your X-11 diet pills" (CX 148; see also CX 184(2)), and Mrs. Ken Schmidt states to Porter & Dietsch that "I talked with you from Walgreen Drug here in Norfolk, Nebraska, last week, about your X-11 diet pills" (CX 147). In publishing these testimonials respondents changed all such product

references to read "X-11 Plan" or "X-11 Reducing Plan," rather than "tablets" or "diet pills."

20. Other members of the public writing to Porter & Dietsch also looked upon what was marketed and advertised as "tablets," "pills" or "reducing pills." Their perceptions of the product are evidenced by the following statements: "I started on your X-11 Tablets. . ." (CX 185); "I called up Saturday for an order of 2 boxes of diet X-11 pills" (CX 186); "We are wondering if we [21] couldn't buy these pills directly from you . . ." (CX 187); ". . . I need these pills" (CX 188); "I received your letter regarding getting X-11 tablets in Sutter Creek" (CX 189); "On occasion my husband has the use of your X-11 diet pills" (CX 190); "X-11 is the only diet pill I have found that works" (CX 191); "I have tried your X-11 tablets for reducing. . ." (CX 192); "I have been taking your reducing tablet for 4 months. . ." (CX 193); "I was on vacation . . . and saw your pills (105)/(X-11) reducing pills so I bought a box. . ." (CX 194); "I used your diet pills about four years ago. . .", "P.S. The name of the diet pills are X-11 reducing plan" (CX 195); "Please send me another box of 42 X-11 Reducing pills. . ." (CX 196); "X-11 is the best reducing tablet sold" (CX 199); "Will you please let me know if there is a place . . . where I can purchase the X-11 reducing Plan pills" (CX 201); "So I tried X-11 and got down to 130 pounds on the first box of pills" (CX 202); ". . .send me some X-11 Reducing Plan Tablets. . .I try some of the other kind of Tablets, but I got sick from them . . ." (CX 203); "In past years I have taken several kinds of reducing pills (from Doctors). All they did was make me nervous . . . But on X-11 there is no after effects" (CX 204); ". . .[i] ordered $5.00 worth of diet pills from you . . ." (CX 206); and, "I would like for you to send me X-11 reducing tablets" (CX 207).

21. The purpose behind the repeated use of the word "plan" in the advertising copy for X-11 tablets, and the use of "X-11 Reducing Plan" as Porter & Dietsch's designation for its product is evident in the letter dated September 13, 1973, to Mr. Fraser, Porter & Dietsch's president, from Mr. Furth, vice-president of respondent Kelly Ketting Furth and the account executive for X-11 tablet advertising (CX 164): [22]

Dear Bill:

. . . . . .

Appedrine is flirting with danger. It is the same kind of danger that hit us in the head in the insurance business.

Appedrine and Hungrex (even Odrinex) put emphasis on the tablets. That's murder, because the pills will not reduce weight an iota.

It is the "Plan" that will keep us out of hot water.

I've said it before. If you want me to put the same kind of "punch" into the advertising, so be it. But we've been getting along swell, without it.

Let them make their claims, we'll make ours. But I'm afraid we're all going to get into hot water because of Appedrine, Hungrex and Odrinex.

Because Hungrex won its case at one time, doesn't mean the sore cannot be reopened.

I've seen it happen in the mail order insurance business.

[23] I don't know if the new 42 line ad will work. That's what tests are for. Ads like Appedrine (from a copy standpoint) may work, but it may put us out of business faster.

• • • • • • •

Cordially,

Joseph Furth
Vice President

22. Labeling the box of tablets the "X-11 Reducing Plan" and including within the tablet box a leaflet (CX 37 and 40) containing a low-calorie diet, a calorie value chart, a table of desirable weights and advice, *inter alia*, that in most cases "obesity is caused strictly by overeating and indiscretions of diet," that "weight loss is only accomplished when a minimum of calories are consumed," that the purchaser must not "expect a miracle overnight" but "must practice a little 'self-denial' — plus, a will power to get thin," and that if the X-11 tablets are taken one-half hour before each meal *and* the "Plan, or any other low-calorie diet" is followed, he or she "should lose weight," does not transform the advertising of "diet pills" into the promotion of a reducing "Plan" so as to mean that no representations were made to the public about X-11 tablets.

23. Respondents were engaged in the advertising, marketing and sale of X-11 tablets. The representations to the public in respondents' advertisements were about X-11 tablets and their efficacy in facilitating weight loss.[5] Such representations were made for the sole purpose of promoting and inducing the sale of X-11 tablets. [24]

ADVERTISING OF X-11 TABLETS

24. Although the pictures, language and format varied, essentially similar statements and themes pervaded respondents' advertisements of X-11 tablets. Respondents agree that "from 1969 to date, the advertising of the 'X-11 Reducing Plan' had remained substantially unchanged" (*see* Memorandum In Support of Motion to

[5] All advertising slicks or mats in the record (CX 50 through 91) were published by respondents in some media (Fraser, Tr. 804 and 883).

Dismiss, etc., filed October 30, 1975, p. 11; *see also* Furth, Tr. 952, 968–69 and 978–80).

25. Porter & Dietsch's advertising expenditures for X-11 tablets were as follows (CX 179):

Year (Ending April 30)	*Dollars*
1975	$882,570
1974	1,082,396
1973	862,986
1972	781,566
1971	593,723
1970	460,902

26. The record contains a large number of advertisements published in various media, predominately newspapers, promoting the X-11 tablets. As noted earlier, five examples have been reprinted in this decision, four large ads and a small one (CX 18–19, 42, 48 and 49), and have already been discussed to some degree. Major metropolitan dailies such as the *Seattle Post-Intelligencer* (CX 1–4), the *Seattle Times* (CX 19), the *Washington Post* (CX 47), the *Baltimore Sun* (CX 46), the *Chicago Tribune* (CX 49) were utilized, as well as smaller circulation newspapers such as the *Anchorage Daily Times* (CX 33), the *Longview Daily News* (CX 21), the *Greensboro Daily News* (CX 74), and the *Peoria Journal-Star* (CX 83). Specialized publications such as *TV Guide* (CX 10–13) were also employed in the dissemination of X-11 advertisements.

27. Ads occupying a small portion of a newspaper or periodical page (CX 5–7, 9, 17, 20–34, 42–43, 51, 54, 64, 77, and 89), as well as very large and prominent advertisements, were published (CX 1–4, 8, 10, 13–16, 18, 35, 44–48, [25] 50, 52–53, 66–76, 78–88, 90–91). Some of the large advertisements were elaborate color inserts known as "free standing stuffers" in the advertising trade (Furth, Tr. 930–33). These were placed in the Sunday editions of the nation's leading newspapers. CX 46 was inserted in the *Baltimore Sun* for Sunday, April 20, 1969, CX 47 in the *Washington Post* on the same date, and CX 49 in the *Chicago Tribune* on February 11, 1973.

REPRESENTATIONS CONVEYED TO THE PUBLIC BY RESPONDENTS' ADVERTISEMENTS FOR X-11 TABLETS

1. *Representation that users of X-11 tablets can lose weight without restricting their accustomed caloric intake and while they continue to eat the foods of their choice*

28. The advertisement published in the *Seattle Times*, September

10, 1972 (CX 18), as indicated, told prospective users that "X-11 is here" and they could "EAT WELL . . . AND LOSE THAT FAT—without ever missing a meal," that they could "satisfy [their] appetite" while taking off "pounds," that they could lose "5, 10, 25 or more pounds" without denying themselves, without dieting hunger, that they would "eat what [they] want," but would eat less because they would not "be the prisoner of the overeating habit."

29. The advertisement published in the *Seattle Times*, July 8, 1973 (CX 19), also told prospective users of the X-11 tablets that they could "EAT WELL . . . AND LOSE THAT FAT." The ad advised that "NO STARVATION DIETING" was required, that unsightly fat could be lost without "suffering through starvation dieting hunger" or following "boring reducing diets," or any of the "humdrum methods you have known and given up." The advertisement told prospective purchasers of X-11 tablets that they could eat "satisfying meals and snacks," that they would not "go to bed hungry," that the "X-11 Plan" was "not a crash or starvation diet" but a "proved and sound method" "to curb the appetite and still eat 3 satisfying, sensible meals [26] a day," and that laboratory science had perfected a "tiny pre-meal tablet" which "lets you eat three sensible meals a day plus 'tween meal snacks."

30. The advertisement published June 24, 1973, in the *Seattle Post-Intelligencer* TV Section (CX 2) likewise featured in black, prominent type "Eat Well . . . Lose That Fat!" The advertisement referred to the "X-11 Plan" as "an extraordinary easy figure-slimming Plan" that offered a way to "get rid of unsightly, superfluous fat" without "missing a meal," and told the prospective X-11 tablet user that she or he could "Satisfy your appetite and peel off those excess, extra pounds, too."

31. The advertisement in the same newspaper on June 25, 1974 (CX 3), was again headed in boldtype "Eat Well . . . And Lose Ugly Fat." This advertisement continued the theme of the earlier ads that X-11 tablet users could "EAT AND LOSE THAT EXCESSIVE WEIGHT," could "satisfy" their appetites and yet "peel off extra pounds" and could remove excessive weight "without ever going hungry." An identical ad was published in the *Seattle Post-Intelligencer* TV Section January 1, 1975 (CX 4).

32. The advertisement in the *Anchorage Daily Times* of March 29, 1974 (CX 8) repeated the statements "Eat Well . . . and Lose That Fat!", that laboratory science had "PERFECTED A TINY PRE-MEAL TABLET WITH A PLAN THAT LETS YOU ENJOY FOODS YOU CHOOSE," that X-11 users could "EAT AND LOSE THAT EXCESSIVE WEIGHT," and could "satisfy" their appetites and "peel off those extra pounds" "without

ever going hungry." Users were promised "you will lose weight . . . while you eat well."

33. The full page advertisement in the *Spokane Spokesman-Review* Sunday Magazine, October 22, 1972 (CX 15), similarly announced "EAT WELL . . . AND LOSE THAT FAT!" "WITHOUT EVER MISSING A MEAL," and "You do not deny yourself." [27]

34. A large advertisement in the *Seattle Times*, February 3, 1974 (CX 45), was headlined "NOW EAT WELL" and "LOSE UGLY FAT!" The text continued this theme with the statement "So enjoy eating that satisfies your appetite as you peel off those extra pounds. You lose weight . . . while you eat well."

35. The elaborate "free standing stuffer" in the Sunday *Baltimore Sun* on April 20, 1969 (CX 46) featured banner headlines which read "Lose Ugly Fat" with an "Amazingly Easy Reducing Plan." The text promised that fat would be lost without "starvation dieting hunger," "boring reducing diets" or "humdrum methods so many women have tried, and given up in despair." Readers were assured that users of X-11 tablets could "now" "EAT AND LOSE WEIGHT," could "satisfy" their appetites yet "remove pounds and inches," could "peel off that excessive weight," and could "Enjoy eating the foods" they chose while they lost "unsightly, superfluous fat." Readers were told in heavy letter type "X-11 IS HERE," and that they could "LOSE UGLY FAT . . . without ever missing a meal!" An identical "free standing stuffer" was inserted in the *Washington Post* on the same Sunday (CX 47).

36. Another advertisement disseminated by respondents announced "Are you on a diet? Or planning to go on one? WHY STARVE YOURSELF WHILE YOU REDUCE? EAT . . . AND LOSE THAT FAT!" (CX 57) Other advertisements told the public "TAKE OFF UGLY FAT WITH AN 'EAT WELL' EATING PLAN" (CX 64). Still others stated "Enjoy eating the foods you choose while you lose excess, ugly fat" (CX 77).

37. The "free standing stuffer" inserted in *The Greensboro Record*, January 26, 1969 (CX 74), featured "EAT WHAT YOU WANT - AND SLIM DOWN," as did the large insert of January 12, 1969, in the *Wisconsin State Journal* (CX 75), and the insert of July 28, 1968, in the *Peoria Journal Star* (CX 83). Other advertisements communicated similar representations, with occasional minor changes in emphasis. See CX 5-7, 9-35, 42-45, and 47-91. [28]

38. Respondents' advertising told the public that with the X-11 tablets people could "EAT WELL AND LOSE THAT UGLY FAT" (CX 2), that X-11 tablets put "enjoyment into eating" while "unsightly, superfluous fat" was lost (CX 52), that overweight persons could take off ugly fat with an "EAT WELL" eating plan (CX 50), and that people

who wanted to lose weight could "eat" and lose "pounds" without dieting hunger, or giving up meals, or by any of the "torturous 500/1000 calorie diets so many women try, and give up in despair" (CX 72).

39. Incorporation deep in the advertising copy of occasional phrases such as users will no longer be the prisoner of the "overeating habit" or that users will "want less" and therefore "eat less" does not change the overall message conveyed to the public. The overall effect of respondents' advertisements was to convey the net impression to the public that users of X-11 tablets could lose body weight without dieting or consciously or materially changing their eating habits, in the language of the complaint, "without restricting their accustomed caloric intake and while they continue to eat the foods of their choice."

2. *Representation that substantially all users of X-11 tablets would lose a significant amount of weight and that Respondents had a reasonable basis from which to conclude this*

40. Although the advertisements for X-11 varied in their format and wording, as stated, the themes remained relatively constant. Purchasers were assured they would realize significant weight losses through use of the X-11 tablets. Respondents' advertisements were of a nature to attract the attention of the seriously overweight, especially women, and to induce them to purchase X-11 tablets in the hope of losing large amounts of excess fat.

41. Representations of significant, indeed, very large, weight losses achievable through the X-11 tablets are prominent in the advertisements respondents disseminated to the public. The impact of these representations is evident by statements recurring throughout the X-11 advertisements, as follows: [29] "I Used to Weigh 160 lbs. Now I'm Down to 105," i.e., 55 pounds lost, (CX 1, 16, 19, and 76); "I lost over 40 lbs.," "And I lost over 40 lbs. too" (CX 1, 16, 19, and 76); "I Lost 80 lbs" (CX 2, 9, 18, 20, 22-24, 30-31, 33-35, 44, and 81); "Lose Ugly Fat" (CX 3, 4, 10, 14, 25-29, 32, 45, 53-56, 60-61, 63-64, 66-67, 74-75, 78-80, 82-84, and 88); "Lose That Fat" (CX 8, 11, 48, 50-51, 57-59, 69-73, 79, 87, and 90-91); "So You Want To Lose 5, 10, 25 Or More Pounds" (CX 1, 14, 48, 58-59, 63, 78-80, 82, and 87); "Get Rid of 5, 10, 25 Or More Pounds" (CX 13, 15, 18, 46-47, 49, 50, 52, 57, 65, 70-75, 83, 86, and 90-91); "Get Rid of Ugly Fat" (CX 42, 77); "Lose 5, 10, 25 Or More Pounds Of Fat" (CX 67, 88); "College Student Lost 83 lbs Of Ugly Fat" (CX 68); "Now. . .Remove Pounds And Inches From

Thighs, Neck, Legs, Waist" (CX 84-85); "I enjoy wearing dresses sizes 11-12's rather than 20 1/2" (CX 44).

42. The X-11 advertisements also conveyed the impression of slimness, and significant weight losses to be achieved through use of X-11 tablets, by pictures of trim-looking women, and silhouettes of slim female figures (CX 1-4, 8-11, 13, 29-31, 33-35, 44-49, 51-56, 58-61, 63, 66-67, 69-76, 78-83, 85, 87-88 and 90-91).

43. Testimonials reporting very large weight losses and implying that new users of X-11 tablets could anticipate like results appeared frequently and were highlighted in respondents' advertisements. These testimonials reported weight losses, as just quoted, of 55 lbs., over 40 lbs., and 83 lbs. (CX 1-2, 9, 16, 18-20, 22-24, 33-35, 44, 68, 76, and 81).

44. Respondents' advertising portrayed the X-11 tablets as a new, simple, easy, amazing, extraordinary way to lose many pounds of fat. The achievement of such weight losses was, in fact, depicted as a virtual certainty. Continual references in respondents' advertisements to "Laboratory Science" having developed a "Tiny Tablet" coupled with the words "NOW," "TODAY," or [30] "RECENTLY" conveyed the impression that the X-11 tablets were the culmination of scientific research, and reinforced the representation that substantially all users could and would lose any amount of pounds desired, up to 80 and 83 lbs. (CX 8, 14, 46-47, 52, 56, 59, 61, 74-75, 79, 83-84, and 87).

45. Significant, large weight losses, in fact, were represented, as "automatic" (CX 74-75):

> So why carry around needless, excess weight — when it's so easy to lose ugly fat *automatically* with the new X-11 Reducing Plan" (Emphasis in original).

The overweight were assured that "thousands of women throughout America are discovering an extraordinary new plan that *automatically* helps get rid of 5, 10, 25 or even more pounds. . ." (CX 74, 75). The public was promised that the X-11 plan "*automatically* keeps working at home, at work, at play — 24 hours a day." (See also CX 46, 47 and 49 which contain similar language.)

46. Significant, large weight losses were guaranteed: "RESULTS ARE GUARANTEED — OR MONEY BACK" (CX 1, 16-17, 19); "[I]f flabby fat doesn't disappear, just return the empty package for an immediate refund" (CX 2 and 81; see also 57-58, and 65-66), and "If flabby fat does not vanish 'like magic' when you follow the X-11 Reducing Plan, just return the empty package for an immediate refund" (CX 15). This theme was constantly repeated in varying language: "LOSE WEIGHT OR YOUR MONEY BACK" (CX 60); "LOSE FAT OR

MONEY BACK" (CX 43 and 77); and "TAKE WEIGHT OFF WITH VERY FIRST BOX OR MONEY BACK" (CX 90). The advertisements repeatedly assured members of the public that "You have nothing to lose but pounds and inches," and that large weight losses would be achieved (CX 24, 50, and 79). [31]

47. Respondents' advertisements for X-11 tablets represented to the public that substantially all users of X-11 tablets would lose a significant, in fact, as large an amount of weight as they desired, and that respondents had a reasonable basis from which to conclude this.

3. *Representation that the X-11 tablets contained a "unique" ingredient*

48. An examination of respondents' X-11 advertising reveals that, through the use of explicit words and phrases, these advertisements conveyed to the public the representation that X-11 tablets contained something new, different and unusual—a "unique ingredient" (CX 3-4, 10, 14-15, 18, 48, 50, 63, 68, 70-80, 82, and 87). Respondents Porter & Dietsch, William H. Fraser, Kelly Ketting Furth and Joseph Furth admitted in their answer that their advertisements represented directly or by implication that the X-11 tablet contained a "unique" ingredient (Ans. P&D, ¶9), and subsequently identified this "unique" ingredient as phenylpropanolamine (Supp. Adm. P&D, No. 41).

49. In addition to specific reference to a "unique" ingredient, many advertisements described the X-11 tablet as: "a unique formula" (CX 8, 10, 14, 48, 59, 67, 78-80, 82, and 87-88); a "unique preparation" (CX 52, 56, 61 and 84-85); a "special formula" (CX 54); a "specialized, laboratory-approved tablet" (CX 74-75); an "unusual combination of ingredients" (CX 49, 52, 56, 61, 74, and 83-85); a combination of "clinic-tested ingredients" (CX 46-47, 49, 74-75, and 83), and "one of the STRONGEST DIET AIDS available without a prescription" (CX 3-4, 10-11, 58, 63, 68, 78, 80, 82 and 88). These phrases were copiously utilized in respondents' advertisements to reinforce the claimed "uniqueness" of X-11 tablets to the purchasing public. [32]

DECEPTIONS IN THE ADVERTISING OF X-11 TABLETS

1. *Users of X-11 tablets cannot lose weight without restricting their accustomed caloric intake nor while continuing to eat the foods of their choice*

50. Excess body weight results from ingestion of more food than the body uses (Dr. Drenick, Tr. 345). A reduction in calories taken in

by the body or an increase in calories used by the body must occur for a person to lose any weight, and the weight lost is directly related to the reduction in calories consumed and/or calories utilized (Dr. Drenick, Tr. 350). However, in programs for the overweight or obese, reduction in caloric intake is emphasized. Dr. Thaddeus E. Prout, an expert in endocrinology and metabolism from Johns Hopkins University Medical School, testified (Tr. 706):

> In general, one does not attack obesity on the outgoing side for the most part, since it is not profitable to try to run off pounds, in the usual sense of the word, without caloric reduction.

For a person to lose a pound of excess fat, a calorie deficit of about 3500 must be incurred (Dr. Margen, Tr. 264).

51. The X-11 tablets do not, and cannot, in and of themselves, remove weight, fat or excess poundage from the human body (CX 164; Dr. Drenick, Tr. 411; Dr. Margen, Tr. 162; Dr. Fineberg, Tr. 1380-82, and 1392-93).

52. As set forth in prior findings, respondents' advertisements represented that X-11 tablet users could "Eat Well" and lose weight, and conveyed the net [33] impression to prospective purchasers that ingestion of X-11 tablets would result in a loss of weight without restriction of accustomed caloric intake and while they continued to eat the foods of their choice. Although this representation was made repeatedly in X-11 advertisements, respondents acknowledged in the package insert that "weight loss is only accomplished when a minimum of calories are consumed" (CX 37, 40, and 133). The leaflet admonished X-11 tablet users not to eat between meals and to follow the diet enclosed with the X-11 tablets "or any other low calorie diet." The diet enclosed with the X-11 tablets provided for a drastically restricted caloric intake. Estimates of the caloric intake permitted under this diet ranged from 650 to 1,000 calories (Dr. Margen, Tr. 169; Dr. Drenick, Tr. 404; Furth, Tr. 986 and 990), and expert witnesses characterized it as a starvation or semi-starvation diet (Dr. Margen, Tr. 169; Dr. Drenick, Tr. 406; Dr. Fineberg, Tr. 1330). Respondents' diet was also described as "ketogenic" and "unphysiologic." Such a diet causes the person following it to experience a feeling of illness and general weakness, and has other undesirable physical effects (Dr. Margen, Tr. 169-72; Dr. Drenick 415-16).

53. Counsel for respondents Porter & Dietsch, William H. Fraser, Kelly Ketting Furth and Joseph Furth admit that users of X-11 tablets "cannot lose weight without restricting their accustomed caloric intake" (Tr. 661).

54. Respondents' advertisements also represented, as described, that users of X-11 tablets could lose weight while continuing to eat the foods of their choice. Porter & Dietsch admit that in order to lose weight users of X-11 tablets must diet and not consume high-calorie foods such as gravies, nuts, candy, mayonnaise, pastries, whole milk, fried foods, rich dressings and rich desserts, and must reduce or minimize their intake of salt, butter and high-calorie foods generally (Adm. P&D, No. 28). The insert in the package of X-11 tablets admonishes X-11 users to take coffee or tea without sugar or cream, to eat no gravy, to trim the [34] fat off all meat, to cut down on cream, butter and other high-calorie foods, and to avoid all fried foods, nuts, candy and rich dressings (CX 37, 40 and 133). This extensive enumeration of dietary restrictions makes it clear that users of X-11 tablets cannot continue to eat the foods of their choice. They must restrict the foods and quantities they consume to those permitted under the X-11 diet or other low-calorie diets. The representations of respondents in their advertisements that users of X-11 tablets could lose weight without restricting their accustomed caloric intake, and while continuing to eat foods of their choice, were false, misleading and deceptive.

2. Respondents had no reasonable basis when they introduced their X-11 tablets and now have no reasonable basis from which to conclude that substantially all users of X-11 tablets would lose a significant amount of weight

55. As stated earlier, the X-11 tablets contain some vitamins, caffeine, methylcellulose and phenylpropanolamine. Users were to take one (1) tablet a half-hour before each meal, and then to follow the menu enclosed in the box of X-11 tablets "or any other low-calorie diet." According to respondents' advertising the X-11 tablets "counteracted hunger," "curbed," "appeased," or "depressed" the appetite, put a "brake" on cravings for high-calorie foods—"everything," and enabled users to adhere to the drastically low-calorie intake provided. The alleged appetite "depressant," "appeaser," "brake" or "diet aid" in the X-11 tablet is phenylpropanolamine, and the alleged hunger "counteracter" is methylcellulose, a vegetable extract. Respondents' advertisements represented that, because of the presence of phenylpropanolamine and methylcellulose in X-11 tablets, all users would achieve significant weight losses of virtually any amount desired. [35]

A. Respondents had conducted no tests, and were in possession of no reports, tests or studies providing a reasonable basis from which to conclude that substantially all users of X-11 tablets would lose a significant amount of weight

56. Individual respondent William H. Fraser, president of corporate respondent Porter & Dietsch, admitted that he had nothing to support the claims made in advertisements for the X-11 tablets. He testified (Tr. 822):

Q. Mr. Fraser, at the time you received that letter and in 1974 what tests or studies or reports of studies or reports of tests or other evidence of effectiveness of the X-11 product did you have in your possession?

A. I did not have any.

Q. Mr. Fraser, at the time the complaint in this matter issued in August 1975, what tests or studies or reports of tests or other evidence of effectiveness did you have in your possession?

A. I had none.

57. In 1969 and 1970 the FDA sent one of its investigators to Porter & Dietsch as a result of the advertising claims which were being published "around the country" (Tr. 904-07). The FDA investigator asked Mr. Fraser for any "information or reports on the efficacy of the product which would indicate that it [36] was effective for the claims that were being made for it" (Tr. 909-10). Mr. Fraser's response was that he had none (Tr. 910).

58. The moving force behind the formation of Porter & Dietsch, and the initiation and marketing of the X-11 tablets, was Frank Gettleman, a Chicago attorney, now deceased. In 1967 he contacted Mr. Fraser, who had just suffered a business reverse, telling him that he had something that Mr. Fraser could make a "comeback" at. At a subsequent meeting in Chicago, Mr. Gettleman told Mr. Fraser about "this diet plan," the X-11 tablets (Tr. 823-24).

59. Mr. Fraser testified that he placed complete reliance upon Mr. Gettleman for having support and authority for the advertising representations made for X-11 tablets. Mr. Fraser testified (Tr. 877):

When Mr. Gettleman sent an ad to me he marked it okay. I did not cross a T nor dot an I. He was the king. He was the man that knew the obesity field. He knew the law. He knew the regulations and I relied entirely on him.

60. Mr. Gettleman had no information, research reports, studies or competent test evidence, which provided a reasonable basis for the representations of weight loss contained in respondents' X-11

advertising. Individual respondent Joseph Furth, who handled the advertising of the X-11 tablets, testified that in 1968, when his firm, Kelly Ketting Furth, took over the X-11 account, Mr. Gettleman showed him two documents (Tr. 1001 and 1006), the 1967 Certification of Record by then Hearing Examiner Poindexter in *Alleghany Pharmacal Corp., et al.*, Dkt. 7176, 75 F.T.C. 990, and the Court of Appeals decision in [37] *Carlay Co.* v. *Federal Trade Commission*, 153 F.2d 493 (7th Cir. 1946). In 1972 when the Commission's staff contacted respondent Pay'n Save Corporation in this matter requesting substantiation of the representations in the X-11 advertisements, the Commission's letter of inquiry (CX 112) was sent by Pay'n Save to Porter & Dietsch for reply, inasmuch as "Pay'n Save had conducted no scientific studies of X-11" (Affidavit of Calvin Hendricks, Executive Vice-President of Pay'n Save Corporation, attached to Motion to Dismiss Complaint Before Trial Or, In the Alternative, For Summary Decision dated November 28, 1975, p. 3). Mr. Gettleman answered this inquiry on behalf of Porter & Dietsch and Pay'n Save, and forwarded to the Commission, as substantiation for the X-11 advertising, copies of the *Alleghany* certification, *supra*, and the *Carlay* decision, *supra* (CX 122-26).

61. In his letter Mr. Gettleman discussed the evidence introduced in the *Alleghany* proceeding, contending that it supported the claims made in respondents' advertising. A thorough reading of the *Alleghany* certification discloses that it does not substantiate respondents' advertising representations of weight losses achievable through the use of their X-11 tablets. The complaint in *Alleghany Pharmacal* did not allege that claims of specific and significant weight losses of virtually any amount from the use of diet pills or tablets were false. The issue was whether "Hungrex" tablets, the active ingredient of which was phenylpropanolamine, had any significant pharmacological value as an appetite depressant or weight-reducing agent, or were adequate or effective in the treatment, control or management of obesity. 75 F.T.C. at 997. The hearing examiner thought that the evidence was conflicting and that the allegations of the complaint had not been established by a preponderance of the evidence. 75 F.T.C. at 1034. On review, the Commission expressly disavowed any opinion "as to the accuracy of [these] findings and conclusions," but dismissed the complaint. The Commission, on the hearing examiner's recommendation, [38] however, ordered that the cease and desist order issued earlier in *Alleghany Pharmacal*, 55 F.T.C. 705 (1958), remain in effect. That order prohibited dissemination of any advertisements for "Hungrex" which represented, directly or indirectly, "that any predetermined

weight reduction can be achieved by taking or use of said preparation for a prescribed period of time." The *Alleghany Pharmacal* case does not provide a reasonable basis for the representations of weight loss contained in respondents' X-11 advertisements.

62. The *Carlay* decision, *supra*, did not provide a reasonable basis for respondents to hold out to substantially all users of the X-11 tablets the prospect of significant weight losses of virtually any amount. The product in *Carlay* was simply a candy-vitamin product, did not contain phenylpropanolamine, and has no bearing whatever on the truthfulness of respondents' advertisements for their X-11 tablets.

B. Medical texts and references provided no reasonable basis from which to conclude that substantially all users of X-11 tablets would lose a significant amount of weight

63. Excerpts from a number of authoritative medical references and texts were received in evidence. Having reviewed their individual and cumulative import, it is the finding of the law judge that they did not provide a reasonable basis from which respondents could conclude that substantially all users of X-11 tablets, containing phenylpropanolamine (25 mg) and methylcellulose (25 mg), would lose a significant amount of weight.

64. The 1962-63 Edition of *Drugs of Choice* by Drs. Walter Modell and George G. Reader (CX 92), a reliable text of widespread circulation and use in the [39] medical profession, devotes an entire chapter to anorexiants and the problem of obesity. The chapter commences by observing that the designation "anorexigenic" to a "group of drugs in common use is unfortunate because it implies a precise pharmacologic action on the central nervous system which has never been demonstrated" (CX 92, pp. 1-2). Taking up the properties of specific anorexiant drugs, Drs. Modell and Reader include phenylpropanolamine in the category of "amphetamine-like drugs" (CX 92, p. 5), note that it tends to elevate blood pressure and that this characteristic "limits its usefulness in the treatment of obesity," and state that (CX 92, p. 7):

> [a]lthough it is used in over-the-counter remedies for obesity, such as Regimen tablets, Du-Dol, and R_x 121, the amount of phenylpropanolamine which they contain is too small to exert any pharmacologic effect at all.

In their 1966-67 Edition of *Drugs of Choice*, Drs. Modell and Reader added to the remarks under phenylpropanolamine concerning "over-the-counter remedies for obesity" that (CX 93):

[t]hese nostrums have been, or are likely to be, removed from the market because of unsupportable and in some cases grossly illegal advertising claims.

An almost identical statement was repeated in the 1972-73 Edition of their text (CX 94).

65. The *Pharmacologic-Basis of Therapeutics* by Drs. Goodman and Gilman, 4th Edition (1970)(CX 95), is another authoritative and reliable text used by the [40] medical profession (Dr. Margen, Tr. 219; Dr. Drenick, Tr. 471). In a section on "Obesity and Weight Reduction," Drs. Goodman and Gilman state that various "sympathomimetic and related drugs" had been used but "[t]hese appetite depressants are of no value without an accompanying stringent dietary regimen," and that "without consistent supervision no prescribed regimen of drug or diet is predictably successful" (CX 95C). Drs. Goodman and Gilman do not include phenylpropanolamine in their list of "anorectic drugs" (CX 95D). In the 5th Edition of their text (1973) (CX 96), Drs. Goodman and Gilman note that "[w]hatever the etiology of obesity, a factor common to all cases is necessarily an intake of amounts of food that supply more energy than the body uses" (CX 96, p. 6). They then repeat statements in the earlier edition that appetite depressants are of "no value" in the areas of obesity and weight reduction without a "stringent dietary regimen." Again, phenylpropanolamine is not included in their discussion of "anorectic drugs" (CX 96, pp. 6-7).

66. The *AMA Drug Evaluations*, First Edition, 1971, published by the American Medical Association (CX 97), is another authoritative and reliable reference work widely used by the medical profession and available to respondents (Dr. Margen, Tr. 219; Dr. Drenick, Tr. 471). This text states bluntly in its chapter on "Anorexiants" that phenylpropanolamine "is probably ineffective in the dose provided (25 mg)."

67. In December 1972, the FDA published and widely circulated a Drug Bulletin titled *Anorectics Have Limited Use in Treatment of Obesity* (CX 101). The FDA's findings applied "to all anorectic drugs," and informed the medical profession and other concerned persons that "all anorectic drugs including amphetamines and methamphetamines" had "limited usefulness in the treatment of obesity." The FDA based its findings on a "unique evaluation of information submitted by the manufacturers of anorectic drugs and a review of the medical literature." After a review of more than [41] 200 drug studies and the records of more than 9,000 patients, the FDA found that "the total impact of drug-induced weight loss over that of diet alone must be considered clinically small," that "patients treated with anorectic drugs lose only a fraction of a pound a week more than those not taking drugs," and that this "weight loss appeared to be related in part to variables other than the drug, such as the physician-investigator, the population treated and the diet selected" (CX 101).

68. As prior findings disclose, respondents' advertisements communicated to the public the net impression that virtually any amount of weight could be lost through use of X-11 tablets, "5, 10, 25 or more" pounds, even 80 or 83 pounds. These are significant weight losses. They are of a magnitude to be impressive to the seriously overweight or obese, and obviously were held out to the public because of that fact, and the capacity of such representations to sell X-11 tablets. In relation to the large amounts of weight loss represented in respondents' advertising as possible through the use of X-11 tablets, the loss of a fraction of a pound a week is insignificant. As Dr. Drenick observed, it "would not be noticeable to anyone who is significantly overweight" and would be medically meaningless (Tr. 386). Further, there is no reason to believe the loss of an additional fraction of a pound would continue for more than a few weeks, even if it were attributable solely to the use of X-11 tablets, because of the development of drug tolerance and other factors (RX 2, p. 206; RX 14, p. 1; Dr. Drenick, Tr. 356; Dr. Prout, Tr. 682).

69. Respondents introduced excerpts from *Drill's Pharmacology in Medicine*, 4th Edition (1971), which referred to phenylpropanolamine as "active enough to be used for controlling the appetite" (RX 4, p. 2), from Martindale *The Extra Pharmacopoeia*, 26th Edition (1972), an English reference work published by direction of the Council of the Pharmaceutical Society of Great Britain, which concluded [42] a descriptive paragraph of phenylpropanolamine by stating it "has also been given to reduce the appetite in obesity" (RX 5, p. 3), and from *Pharmacology and Therapeutics*, 7th Edition (1970), by Drs. Grollman and Grollman who state that phenylpropanolamine "is used . . . to depress appetite in obesity" (RX 6, p. 2). Dosages for use as an anorectant were not listed in these references.

70. The medical texts and references in the prior finding do not provide support for significant weight losses of virtually any amount held out by respondents' advertising to purchasers and users of X-11 tablets. That a drug is "used" for a purpose cannot be equated with effectiveness for that purpose (Dr. Margen, Tr. 307; Dr. Drenick, Tr. 471). But even if the references in the foregoing finding were to be taken as evidence that phenylpropanolamine had some effectiveness as an appetite suppressant, it does not follow that substantially all users of X-11 tablets would lose a significant amount of weight.

C. Expert testimony disclosed no reasonable basis in medical science from which to conclude that substantially all users of X-11 tablets would lose a significant amount of weight

71. The state of medical experience, knowledge and understanding generally, and in the field of obesity and its treatment, did not provide respondents with a reasonable basis for the representations of weight loss contained in respondents' X-11 advertising. The record contains the testimony of three expert medical doctors, called by complaint counsel, who had long-term experience in the treatment of obesity. Additionally, complaint counsel called an FDA pharmacologist who [43] testified in connection with the FDA Drug Bulletin (CX 101). Respondents called three experts, a medical doctor, a professor of pharmacology, and a professor and researcher specializing in physiological psychology. The testimony of these experts viewed overall discloses no reasonable basis in medical science, in the opinion of the law judge, for respondents to conclude that substantially all users of X-11 tablets would lose a significant amount of weight.

Medical Doctors

Dr. Margen

72. Dr. Sheldon Margen, called by complaint counsel, is a Professor of Human Nutrition, and the 1970-74 Chairman of the Department of Nutritional Sciences, at the University of California at Berkeley. After majoring in zoology and receiving a Master's degree in that science and experimental embryology, he graduated from the University of California Medical School in 1943, and was licensed to practice medicine in California the same year. Dr. Margen subsequently has had a distinguished medical career involving private practice, teaching, lecturing and, in particular, extensive research. He is an authority in the field of human nutrition, metabolism, and the treatment of obesity, and has individually and jointly authored over 85 scientific papers, many in the fields of his expertise. In addition, Dr. Margen has written chapters for a number of scientific texts, and has participated in the writing of a number of others (CX 110). Currently, he is operating, with other researchers at the University of California, a controlled metabolic unit funded by the National Institutes of Health where metabolic studies in human nutrition are conducted. He is also participating in an ongoing, multi-disciplinary obesity program

conducted on an outpatient basis at the University (Dr. Margen, Tr. 129 and 141-43). [44]

73. In Dr. Margen's expert opinion drugs have "no place in the treatment of obesity" because it is not a simple problem capable of being cured by a pill (Tr. 162). If there were a "magic pill," in Dr. Margen's view, "obesity would have disappeared by now" (Tr. 162). Drugs in the treatment of obesity are "essentially placebos in their effect," and are not a helpful or proper therapeutic approach (Tr. 163). According to Dr. Margen, phenylpropanolamine is essentially a placebo, and is useless in treating obesity (Tr. 164-65, 292-95 and 299-302). Dr. Margen saw "no reason to get an individual started" on drugs such as phenylpropanolamine (Tr. 296):

> . . . when the very slight gain which may occur early can just as well be taken care of and overcome by the sympathetic working with a person instead of relying upon just handing out a drug or prescription.

Dr. Margen's opinion that drugs such as phenylpropanolamine are useless in the treatment of obesity are based upon his research and experience over a ten (10) year period, "I would say after about ten years of trial, I gave them up" (Tr. 255).

74. Dr. Margen testified that he agreed (Tr. 241) with the statements under "Obesity and Weight Reduction" in *The Pharmacologic Basis of Therapeutics* (CX 95 and 96) to the effect that appetite depressants were of "no value" in weight reduction "without an accompanying stringent dietary regimen," and that it had been regularly demonstrated that "without consistent supervision" no prescribed regimen of diet is "predictably successful." Dr. Margen also agreed with the *AMA Drug Evaluations* (CX 97) that phenylpropanolamine was "probably ineffective" as an anorexiant in the dose of 25mg provided in X-11 tablets (Tr. 242-43). Dr. Margen testified that epidemiological studies had shown the [45] "break point" between obesity having adverse effects upon health and not having adverse effects upon health was around 20 percent overweight (Tr. 150). Accordingly, Dr. Margen defined a "significant" loss of weight from an epidemiologist's viewpoint as one which returned an individual's weight to "the area of the so-called safe level" (Tr. 151).

Dr. Drenick

75. Dr. Ernst J. Drenick, called as an expert witness by complaint counsel, is a Professor of Medicine at UCLA Medical School, heads the UCLA obesity clinic, and is Chief of Internal Medicine at the Veterans Administration Hospital, West Los Angeles. He graduated

from New York University College of Medicine in 1941, and has been on the faculty of UCLA medical school since 1955. Dr. Drenick's special interest is nutrition and metabolic diseases, and his primary work has been in the field of obesity (Tr. 340-41). He has been involved in the study of obesity since 1962, and from that year to the present has studied overweight patients, admitting them to the hospital and determining how they responded to various nutritional and weight-reduction programs, their needs for vitamins and different food items, and the effect of various treatment methods. He handles an average of 60 to 70 hospitalized patients and 200 to 300 outpatients each year. Hospitalized patients are admitted for two to four months each, and are carefully observed from the standpoint of psychological responses to various methods of treatment, psychologic makeup, including the reasons for abnormal eating habits, and how such habits can best be remedied (Tr. 341-42). He is supported by several technicians, two of whom are graduate students with advanced degrees, and at times is assisted by graduate fellows who are M.D.'s or Ph.D.'s (Tr. 342). Dr. Drenick is an authority in the field of obesity and its treatment. He has written or co-authored 50 scientific papers, most of which have [46] dealt with obesity, weight reduction and associated subjects, including the various psychological processes of obese individuals (CX 114). Dr. Drenick also has prepared chapters for two medical textbooks and performs editorial services as a reviewer for the *Journal of the American Medical Association*, *American Journal of Clinical Nutrition*, the *Journal of Laboratory and Clinical Medicine*, the *Annals of Internal Medicine*, *Gastroenterology*, *Metabolism*, and *Obesity and Bariatric Medicine* (CX 114; Tr. 344-45).

76. Dr. Drenick has been unable to achieve permanent weight reduction and maintenance of normal weight with "any of the so-called appetite suppressants." The only way this has been accomplished has been through dietary restriction in conjunction with increased activity levels, and "prolonged educational programs to re-educate the patient to normal eating habits." Such re-education requires a close, ongoing relationship between the patient and the individual supervising his or her progress (Tr. 353). Without such supervision the results are "pitiful" (Tr. 354). Over a period of two years better than 90 percent of those treated return to their original weight or have increased beyond what they started with (Tr. 354). Without continuing "follow-up" the failure rate is "almost universal" (Tr. 354-55). In Dr. Drenick's experience the obese patient has to be taken under the care of a doctor or leader of a weight-reduction program, such doctor or leader has to make sure the patient is well

motivated, and such motivation has to be maintained to make sure the patient does not "backslide" (Tr. 355).

77. Dr. Drenick knew of no drug that had "significant results or benefits in weight reduction." Drugs in the "appetite suppressant family," such as phenylpropanolamine, "have a very limited span of effectiveness even if a mild effectiveness were present" (Tr. 356). In Dr. Drenick's professional experience (Tr. 356): [47]

> The weight loss usually is very, very minor and at the end of five or six weeks the patient realizes that the drug isn't doing any good. He becomes disappointed and is no better off and perhaps worse off.

78. Dr. Drenick agreed with statements in the medical literature that phenylpropanolamine was "ineffective" in achieving weight loss, and shared the opinion that "it should not be used in the treatment of obesity" (Tr. 368-69). Dr. Drenick also agreed with *Drugs of Choice* (CX 92, 93 and 94) testifying that phenylpropanolamine was "of questionable value or of no value" (Tr. 369). He further agreed with *AMA Drug Evaluations* (CX 97) that phenylpropanolamine was "probably ineffective in the dose provided (25 mg)" (Tr. 372).

79. Dr. Drenick testified that a "significant" weight loss must be a weight loss which was meaningful to the patient and significant from a clinical point of view (Tr. 356). To illustrate, Dr. Drenick cited the case of a 350-pound patient who lost 5 or 6 pounds. Such a weight loss was measurable on the scales, but "for the patient medically, it is totally insignificant" (Tr. 357). Dr. Drenick testified (Tr. 357):

> You can say, well, I have given him amphetamines, he has lost seven pounds in weight. Therefore, that is a great result. It is totally insignificant medically but statistically you can say there was a significant weight los[s]. [48]

Dr. Prout

80. Dr. Thaddeus Prout, the third medical expert called by complaint counsel, graduated from Harvard Medical School in 1948. After training in general internal medicine, he studied for three additional years as a fellow in the fields of endocrinology and metabolism. He is currently Chief of Medicine, Greater Baltimore Medical Center, and Associate Professor of Medicine at Johns Hopkins University School of Medicine. Dr. Prout has taught at Johns Hopkins for many years, and for a period was a full-time faculty member. He is currently Director, Metabolic Division, Moore Clinic, The Johns Hopkins Hospital; Consultant in Endocrinology, Veterans Administration Hospital, Perry Point, Maryland; Consultant in Endocrinology, Veterans Administration Hospital, Baltimore, Maryland; Consultant, Department of Health, Education and

Welfare; Consultant, Food & Drug Administration, National Institutes of Health; and has served as a consultant for the Bureau of Dangerous Drugs and Narcotics (CX 119; Tr. 670). Dr. Prout is an authority in the fields of endocrinology and metabolism, and is Chairman of the FDA's Committee on Endocrine and Metabolic Drugs (Tr. 668-72; CX 119).

81. In 1972 Dr. Prout headed a panel of experts established to advise the FDA on the safety and efficacy of anorectic drugs (CX 120; Tr. 680). This panel, "Consultants on Anorectic Drugs," reported to the FDA in the Fall of 1972 (CX 120). The report of Dr. Prout's panel resulted in the "FDA Drug Bulletin" being circulated to the medical profession, and to other interested groups and organizations in December 1972 (CX 101; Tr. 687).

82. The advisory panel of experts chaired by Dr. Prout reviewed the "best evidence available" on anorectic drugs and all the information submitted to [49] the FDA, including studies, tests, and histories of individuals involving "something in excess of 10,000 patients" (Tr. 723-27). The drugs studied by the panel included amphetamine-related drugs, known also as sympathomimetic amines. Phenylpropanolamine is of the same class although it was not specifically a subject of the panel's study (Tr. 676). The amphetamine-type drugs studied were stronger than phenylpropanolamine in their effects on the human body. According to Dr. Prout "[a]ll the evidence that we have suggests that it is less potent as an anorectic agent than is the parent compound" (Tr. 708). The panel's findings applied to "all anorectic drugs" including phenylpropanolamine (CX 101).

83. Although there were some members "who would have preferred to make the statements stronger than we made them" (Tr. 727), Dr. Prout's panel of experts were in agreement that anorexiants had a "clinically trivial" effect on weight loss (CX 120). The "increased weight loss of drug treated patients over placebo treated patients was only a fraction of a pound a week," and the panel concluded that ". . .the total impact of drug-induced weight loss over that of diet alone must be considered clinically trivial" (CX 120). Dr. Prout testified that the panel, after reviewing the massive amount of data available to it, found (Tr. 681-82):

> . . .that in general, one would see somewhere between 0.3 to 0.4 pounds per week on the average for these short term studies. Considering the fact that many of these patients were 100 percent over body weight, that was, in fact, a trivial reduction in their total body overload.

Losses of 0.3 or 0.4 of a pound a week applied for short periods and would tend to decrease for greater time periods (Tr. 682). [50]

84. The final report to the FDA by the "Consultants on Anorectic Drugs" stated that the possible origins of the small weight loss described in the preceding finding were not established and that (CX 120):

> . . .The increased weight loss appears to be related to variables other than the drug prescribed, such as the physician-investigator, the population treated, and the diet prescribed. Studies do not permit conclusions as to the relative importance of the drug and non-drug factors on weight loss.

85. Dr. Prout considered that a weight loss due to the action of an anorexiant or other drug, that is, the "additional effectiveness of an anorectic agent over that of a placebo or diet plus placebo" of a pound a week would be "clinically useful and quite significant," but such a drug or agent "is certainly not known at the present time" (Tr. 690-91). He had used anorectic drugs in treating overweight persons in the course of his medical practice, but "without any success" so he had discontinued them "having found no usefulness for them" (Tr. 722-23)..

Dr. Fineberg

86. Dr. Seymour K. Fineberg, an expert medical doctor called by respondents, is a physician practicing in New York City and specializing in internal medicine with particular emphasis in the fields of diabetes, obesity or metabolic disease, and cardiology. He graduated from the University of Arkansas in 1936 and obtained his M.D. in 1940. After receiving his M.D. he spent two years in a general rotating internship, followed by a two-year residency in internal medicine, [51] and then graduate study in basic sciences at New York University School of Postgraduate Medicine (Tr. 1313). He is currently Clinical Associate Professor of Medicine at New York Medical College. Dr. Fineberg has served as a consultant in the field of anorexigenic drugs, and has advised pharmaceutical manufacturers who were evaluating anorexigenic drugs presently on the market (Tr. 1314). He has been a consultant for the AMA Council on Drugs and worked on the chapter on anorexigenic agents in the 1973 Edition of *AMA Drug Evaluations*. Dr. Fineberg has published about 40 medical papers, the bulk of them being in the fields of obesity, diabetes and nutrition (RX 44; Tr. 1314). He has a private practice, some of which relates to obesity, which takes about 25 percent of his time (Tr. 1315).

87. Dr. Fineberg became interested in appetite suppressants in

the treatment of diabetes in 1958. He wrote an article, "Obesity-Diabetes and Anorexigenics," published in the *Journal of the American Medical Association* in February 1961 in which he reported that phenmetrazine hydrochloride and diethylpropion were "significantly anorexigenic" (RX 43). Although Dr. Fineberg believed that anorexiants relieved the symptoms of hunger and produced weight loss (Tr. 1325-26, 1328-29, 1344), phenylpropanolamine has not been among the drugs used or studied by him (Tr. 1323, 1336). Dr. Fineberg's knowledge of phenylpropanolamine is based on its molecular structure and the fact that it is a member of the phenethylamine group (Tr. 1342).

88. In another article, "Anorexiant Drugs In Perspective," published in 1967 in the *Journal of the American Geriatrics Society* (RX 46), Dr. Fineberg sought "to teach the medical profession where they have been making mistakes in the treatment of obesity and in their use of appetite suppressants," that those drugs were widely used "despite what all has been said about them," and that "if they do have a small but definite role to play" they "should be used properly" [52] in order to "obtain the right effect in the overall treatment of obesity" (Tr. 1348-49). In this article Dr. Fineberg stated that anorexigenic drugs were useful "only during the initial, relatively short weight-reduction period in the course of lifetime control," and that the "sole purpose" of the drug was "to provide symptomatic relief" (RX 46, p. 3). In concluding his article Dr. Fineberg states (RX 46, p. 7):

> The anorexigenic drug plays a relatively short, minor, though often integral, role in the treatment of obesity, a disorder which requires lifetime control and cannot be cured. The foundation for permanent weight control is an education in calories, dietetics and nutrition and in the acceptance of a new way of life. Appetite suppression by drugs is used only to relieve the discomfort of caloric restriction during the early stages of education and mental adjustment.

Dr. Fineberg did not mention phenylpropanolamine in his discussion of "anorexiant" drugs, although many others are described or mentioned including dextro-amphetamine, methylamphetamine, phenmetrazine, and diethylpropion.

89. In an article in *Drug Therapy* in March 1973, cast in a question and answer format, Dr. Fineberg wrote that the only purpose of appetite suppressing drugs was to "relieve the symptoms of physiologic hunger," and they were only a "crutch" to help an obese patient beyond the initial phase of treatment (RX 45). He stated that obesity should be thought of as a condition "which requires continuous treatment," and that anorexigenic drugs are not useful in helping a patient maintain an initial weight loss, but are

only useful "to relieve [53] the discomfort associated with dieting." All in all, Dr. Fineberg felt that the medical profession did not have a great deal to offer the obese patient (RX 45). Dr. Fineberg also testified that he believed appetite suppressants had an effect, and if properly used and properly presented to an obese patient, often meant "the difference between success and failure in the treatment of a patient's obesity" (Tr. 1329). The appetite suppressants do not take off weight but, in Dr. Fineberg's opinion, the "symptoms are relieved that are produced by hunger" (Tr. 1322).

90. Dr. Fineberg used prescription drugs such as phenmetrazine, dextroamphetamine, and diethylpropion as appetite suppressants (Tr. 1382). He had never been impressed by anything he read about phenylpropanolamine as an anorexiant, and had never used it, explaining that he wanted to use a drug "most likely to succeed and do the job that I am asking it to do" (Tr. 1384; see also Tr. 1336, 1341 and 1383). He "had no interest in going to an older member of this family which had never been thought to be a very strong or potent member of that family" — "Why should I go back and use something which I feel is not as efficacious as the one I had in hand" (Tr. 1383). Dr. Fineberg could not say whether phenylpropanolamine was effective in a 25 mg dosage tablet for the "normal run of people" (Tr. 1384). However, based on its molecular structure and upon medical references, Dr. Fineberg believed it to "have some anorexigenic properties" (Tr. 1342). Nevertheless, Dr. Fineberg testified that it would be "impossible" for him to predict what effect the ingestion of a tablet containing phenylpropanolamine prior to a meal would have on the food eaten by a person at such meal (Tr. 1352 and 1384). The dosage of an appetite suppressant of any type, in Dr. Fineberg's experience, is a "widely variable thing individually" and must be "tailored to the individual" (Tr. 1345, 1352 and 1388). [54]

Other Experts

Dr. Silverman

91. Dr. Harold I. Silverman, a Professor of Pharmacology at Massachusetts College of Pharmacy, the Massachusetts College of Optometry, and Boston University Medical School, was called as an expert witness by respondents Porter & Dietsch, William H. Fraser, Kelly Ketting Furth and Joseph Furth. He has published approximately 75 articles and a text on pharmacology. Dr. Silverman graduated from the Philadelphia College of Pharmacy in 1952 where he also received his Ph.D. in 1956 (RX 35; Tr. 1101-04). He is not an M.D. and does not treat patients for overweight or obesity.

92. Among Dr. Silverman's publications is an article published in the *American Journal of Pharmacy* in 1963 entitled "Phenylpropanolamine–Misused? Or Simply Abused?" (RX 36). Dr. Silverman testified that his main purpose in writing this article was to criticize the "Fazekas" report, published in 1959, which had concluded that phenylpropanolamine was ineffectual as an appetite suppressant (Tr. 1148). Dr. Silverman reviewed the literature, both national and international (Tr. 1105), and wrote that of all the anorexiants, amphetamine and its analogs are the most effective (RX 36, p. 3). Reviewing the literature, Dr. Silverman found favorable, as well as unfavorable, comments regarding the appetite-suppressant qualities of phenylpropanolamine, noting in the process that the FDA had "gone on record" in stating that phenylpropanolamine was "worthless as an appetite depressant" (RX 36, p. 8). One of the references listed by Dr. Silverman (RX 36, p. 11, note 15) was a 1939 article which he quoted as reporting that phenylpropanolamine was "[e]ffective in controlling the appetite of patients on an obesity diet." The author of this article, Dr. Hirsh, had later testified publicly before a Subcommittee of the House Committee on Government Operations investigating advertising of weight reducing [55] products in 1957, six years before Dr. Silverman's article was published, and had changed his opinion. See *False and Misleading Advertising* (Weight Reducing Preparations), *Hearings before a Subcommittee of the Committee on Government Operations*, House of Representatives, 85th Cong., 1st Session, August 2, 6, 7 and 8, 1957, pp. 56–63. Dr. Hirsh stated to the House Subcommittee that firms marketing reducing pills "endeavor to exploit phenylpropanolamine," and that a dose of 25 mg of phenylpropanolamine taken three times daily "would exercise no appetite depressant effect of significance for the great vast majority of persons." Although Dr. Silverman's article referenced (RX 36, p. 11, note 7) the Committee hearings, the disparity between the foregoing statement of Dr. Hirsh before the House Committee in 1957, and the 1939 article quoted by Dr. Silverman, was not noted. In concluding his article, Dr. Silverman made a number of points critical of the "Fazekas" study, questioning whether that study warranted condemnation of phenylpropanolamine, but making no claims of specific amounts of weight loss associated with that drug.

93. Dr. Silverman testified that, in his opinion, phenylpropanolamine is effective as an appetite depressant in 75 mg daily dosages (three X-11 tablets), and that use in conjunction with a dietary program of 1,200 calories per day would bring about a significant decrease in weight with time (Tr. 1107). He also testified that he had

no question that anorectic preparations were very useful in helping individuals lose weight (Tr. 1111). Dr. Silverman regarded statements questioning the value of anorectic drugs or describing them as placebos as "frequently made unfortunately because of certain intimidation that has occurred in the field of drug therapy" and because there is "unfortunately a small group of persons who try to develop their opinions and unfortunately sometimes manage to get their opinions published in the literature" (Tr. 1110). [56]

94. Dr. Silverman had conducted a study evaluating phenylpropanolamine and a placebo over a several week period (RX 3). He concluded that phenylpropanolamine was effective as an anti-obesity agent when used as it was in his study (Tr. 1120). Dr. Silverman's study was received in evidence, and will be considered in the following section of this decision along with studies of Dr. Hoebel.

95. Dr. Silverman agreed with the statements in *Drill's Pharmacology in Medicine* (RX 4), *The Extra Pharmacopoeia* (RX 5), and *Pharmacology and Therapeutics* (RX 6), that phenylpropanolamine is used in the treatment of obesity (Tr. 1108-09). Referring to the *FDA Drug Bulletin* (CX 101), Dr. Silverman testified that he was familiar with this publication and its conclusions. He testified that the FDA had concluded "that anorectic drugs are acceptable and useful agents for the reduction of appetite and useful as a proven measure for those people who are obese" (Tr. 1111). In fact, the *FDA Drug Bulletin*, as earlier described, concluded that anorectic drugs were of "limited usefulness" in the treatment of obesity, that their effects "must be considered clinically small," that patients treated with such drugs lost "only a fraction of a pound a week more than those not taking drugs," that the fraction of a pound weight loss of those taking drugs "appeared to be related in part to variables other than the drug," and that the weight loss "declines in succeeding weeks" (CX 101).

Dr. Hoebel

96. Dr. Bartley G. Hoebel is a physiological psychologist, and a Professor in the Department of Psychology at Princeton University. His field of specialization involves the study of the relationship between brain and behavior. He obtained his Ph.D. at the University of Pennsylvania in 1962, and taught at [57] that institution briefly before moving to Princeton in 1963 where he became a full professor in 1970 (RX 37; Tr. 1176-77). He has authored or co-authored about 35 publications (RX 37).

97. Dr. Hoebel testified it was his opinion, based on his studies, that "people interested in weight loss and knowing that a pill might

be involved in suppressing appetite is being [sic] under test" will eat less (Tr. 1195), and that "people taking this pill [containing phenylpropanolamine] will lose some [weight], on the average, and that individuals, some individuals will lose a lot" (Tr. 1296). People following a restricted diet would be happier, according to Dr. Hoebel, if they used an appetite suppressant, but the effects of the diet and the appetite suppressant have not been scientifically demonstrated to be additive (Tr. 1199-1200). Dr. Hoebel emphasized, however, that his studies demonstrated the effectiveness of phenylpropanolamine to bring about weight loss only under the conditions of his experiments and for short time periods (Tr. 1241).

98. Contrary to his earlier statement, published as recently as 1975, that phenylpropanolamine "has never adequately been proven effective" (RX 41, p. 7-8), Dr. Hoebel in this proceeding stated that such proof existed. Recent studies by himself, Dr. Silverman and a Dr. Palmer, according to Dr. Hoebel, support the view that phenylpropanolamine is an effective anorexiant (Tr. 1205).

99. Dr. Hoebel disagreed with statements made in *Drugs of Choice* that phenylpropanolamine is ineffective in 25 mg dosages, that obesity is a "singularly human trait," and could be of psychiatric origin and therefore not amenable to treatment with drugs. He also disagreed with the statement that no anorectics are effective without simultaneous control of food intake (Tr. 1223-24). Dr. Hoebel testified that these and [58] other statements of Dr. Modell's were "based on old, inadequate studies which have led him to false conclusions, numerous false statements and a basic bias" (Tr. 1220). Dr. Hoebel also testified that the other medical references referred to during his questioning suffer the same defects as *Drugs of Choice* since they rely on this major work for the accuracy of their statements. Dr. Hoebel testified that medical textbooks lead people to conclude that phenylpropanolamine is not effective because they were written (Tr. 1225):

> . . .without access to the current or the latest data and in some cases, by people who had very strong prejudices about the nature of obesity in humans and the fact that in their minds, it is something that is psychic and not amenable to drug treatment.

Dr. Hoebel's studies (RX 1 and 2) will be considered in detail in the following section of this discussion.

Dr. Sorer

100. Dr. Heinz Sorer, called as an expert by complaint counsel, is a pharmacologist on the drug abuse staff of the FDA, Division of Neuropharmacological Drug Products (Tr. 616). Dr. Sorer's work

entails safety evaluations of drugs, including appetite suppressants, which affect the central nervous system (Tr. 617). Between 1966 and 1972, Dr. Sorer was concerned with an evaluation of sympathomimetic amines undertaken by the FDA to gather information regarding potential abuse of these drugs, and to formulate an FDA policy regarding evaluation of their efficacy (Tr. 618-19). The culmination of this FDA effort was CX 101, the *FDA Drug Bulletin*, discussed in detail earlier herein by Dr. Prout who headed the expert panel evaluating these drugs. Dr. Sorer testified that the effects of the sympathomimetic amine drug group, of which phenylpropanolamine is a member, varied "from individual to individual" (Tr. 630). [59]

D. Studies by experts called by respondents did not provide a reasonable basis from which to conclude that substantially all users of X-11 tablets would lose a significant amount of weight

The studies of phenylpropanolamine by respondents' expert witnesses, Drs. Silverman and Hoebel, were received in evidence, being offered by respondents as substantiation for the weight-loss claims made in X-11 advertisements (RX 1, 2 and 3)

(a) *Dr. Silverman's Study*

101. "A Double-Blind Clinical Evaluation of a Phenylpropanolamine-Caffeine-Vitamin Combination And A Placebo In The Treatment of Exogenous Obesity" (RX 3), published in *Current Therapeutic Research*, Vol. 17, No. 6, June 1975, is a study which Dr. Silverman conducted in collaboration with two medical doctors. Inasmuch as this study was published in June 1975, it obviously could not have provided a reasonable basis for claims for X-11 tablets in advertisements of respondents disseminated in 1968 and subsequent years prior to its publication. Nevertheless, such a study would bear upon the propriety of an order in this proceeding if, in fact, it provided a reasonable basis for the advertising claims. This was not the case, however, for Dr. Silverman's "double-blind" study had some dubious aspects, raising questions as to the reliability of its conclusions. Furthermore, even if this were not the case, the study did not provide a reasonable basis for the representations in respondents' advertisements that users of X-11 tablets could lose significant, large amounts of excess weight of virtually any amount. [60]

102. Two allegedly parallel groups of exogenously obese adults

were employed in the study. One group was given a test preparation containing phenylpropanolamine (25 mg), caffeine and multi-vitamins while the other group received a placebo tablet. Both groups were also given a 1,200 calorie diet plan and instructions on its use. Dr. Silverman reported that over a "four-week period" while on the test preparation the "median" weight loss of males was 3 1/2 pounds greater than males on the placebo. The "median" weight loss of females on phenylpropanolamine was 2 pounds greater than the median weight loss of females on the placebo. Dr. Silverman concluded that the results produced a "statistically significant difference at the < 0.05 probability level in the weight loss of females using the test preparation compared to those using the placebo," but "no significant difference in the case of males" (RX 3, pp. 538–39).

103. Both Dr. Margen and Dr. Drenick analyzed the study of Dr. Silverman (Dr. Margen, Tr. 209–17; Dr. Drenick, Tr. 390–98). Dr. Margen found that the combined treatment group had a difference of 1 1/2 pounds in 4 weeks which comes out at a .05 probability, the lowest possible range of significance, "you can't have anything worse than that in terms of probability" (Tr. 213). Dr. Margen further found that the greatest weight loss of anyone in the study occurred in a female who was on the placebo (Tr. 213). Among the males in the study "there was no significant weight loss between the placebo and the PPA [phenylpropanolamine]" (Tr. 214). Dr. Margen testified (Tr. 214):

> What is even more important is that, in the case of the males, there was no significant weight loss between the placebo and the PPA. In the case of the females, again, it was at the 10 to 20 probability range and certainly statistically in one case absolutely nothing happened. Clinically you have a weight difference which is of [61] absolutely no significance and, lastly, and I think what was sort of curious, the tremendous variability which you see in patients losing weight, and if one wants to make a joking point one can say that the greatest weight loss was with the female on the placebo."

104. Dr. Silverman reported his results in terms of a "median." In Dr. Drenick's professional judgment, use of a median to assess weight changes in such a study is unacceptable as it is not a proper scientific method for evaluating the test results (Tr. 390 and 398). This is a serious defect in the study because, as Dr. Drenick testified (Tr. 392–93):

> Another reason why this study is uninterpretable to me is that the authors used a way of assessing weight changes that are really not acceptable. They talk about median weights and median weight losses.

. . . . . .

> A median weight loss of eight pounds means absolutely nothing because I don't know what the other people on this side or on this side of the man in the middle lost. Since all of the weight losses are given as median weight loss I really don't know what he is talking about and I cannot say what his conclusions are or have any meaning at all.

(See also, Dr. Margen, Tr. 212). [62]

105. The characteristics of the subjects who participated in Dr. Silverman's study were so varied in their body builds and weights as to render meaningless the fractions of a pound of weight loss per week Dr. Silverman attributed to phenylpropanolamine (Dr. Drenick, Tr. 391–92). The females in the group on the test preparation had a median starting weight 12 pounds heavier than the median starting weight of females in the placebo group. Dr. Drenick testified that heavier individuals tend to lose more weight when following a diet simply because their caloric deficit is greater (Tr. 391). Dr. Drenick found that almost half (46 percent) of the females on the placebo were small framed, compared with one-quarter (24 percent) of those on the test preparation. Only 17 percent of the placebo group females were heavy framed contrasted with 32 percent of the group on the test preparation (Tr. 390–92). This is significant since "a small framed individual who is overweight carries a lot more fat" than a heavy framed individual (Tr. 391). The test groups were so dissimilar in significant characteristics as to render the study meaningless. Dr. Drenick testified (Tr. 392):

> This may be an accident in their selection but it certainly is not true that these are comparable groups and for this reason any assessment of differences in weight loss is meaningless because you are not judging identical groups. They are totally dissimilar.

106. The small weight losses reported by Dr. Silverman of those on the test preparation over those on the placebo may even have been due to a diuretic effect (Dr. Drenick, Tr. 393–94).

107. Dr. Silverman's study further assumed that the crucial period in any reducing regimen was "usually during the initial part of the program" (RX 3, p. 541). [63] This is contrary to the prolonged and extensive experience of both Drs. Margen and Drenick in treating obese and overweight persons. Dr. Drenick testified (Tr. 397):

> Everyone knows that obese individuals go on diets time after time after time and usually they lose a few pounds in the first few days. But the extended period, the long haul, this is where they fail.

Dr. Margen testified that to say the initial period of a dietary

regimen was the most crucial period was wrong "because the most crucial period is the long-term period" (Tr. 214). According to Drs. Drenick and Margen, Dr. Silverman thus tested phenylpropanolamine in the period where it is easiest to lose weight, and did not follow his test subjects over a more extended period of time.

108. Additional and thoroughly complete professional evaluation of the results published in this study were made impossible by Dr. Silverman's refusal to allow complaint counsel an opportunity to examine the study's underlying data (Tr. 1131).

109. Dr. Silverman's study, in any event, provided no basis for respondents' representations of weight loss from use of their X-11 tablets. Loss of one-half, or less than one-half a pound a week, over a 4 or 5-week period for an obese person is "clinically trivial" (see CX 101, 120), particularly in the absence of evidence that such loss can be continued.

(b) *Dr. Hoebel's Studies*

110. Dr. Hoebel, whose testimony has already been discussed to some extent, conducted experiments involving phenylpropanolamine with both animal and human [64] subjects. Before conducting studies with human subjects Dr. Hoebel experimented with phenylpropanolamine on rats. Four of his studies with rats were offered by respondents and received in evidence (RX 38-42). Dr. Hoebel's experiments with rats involved doses of phenylpropanolamine 100 to 1,000 times greater, on a relative basis, than the standard 25 mg dosage used with human subjects, and in many of the animal experiments the drug was injected directly into the brain (Dr. Margen, Tr. 186). Under these circumstances, loss of appetite or weight loss obtained by Dr. Hoebel in rats does not imply similar results in humans from oral ingestion of far smaller amounts of phenylpropanolamine. Moreover, overweight or obesity in humans derives from a variety of causes to which rats are not subject. As Dr. Drenick testified (Tr. 396):

. . .making a rat lose weight does not mean that you are going to have a human losing weight because obviously humans overeat for reasons that are totally different from a rat.

111. Dr. Hoebel has published two papers dealing with human subjects, "Appetite Suppression By Phenylpropanolamine In Humans" (RX 1) and "Body Weight Decreased In Humans By Phenylpropanolamine Taken Before Meals" (RX 2), both in *Obesity/Bariatric Medicine*, Vol. 4, No. 5, 1975. From the foregoing date it is clear that these are recent studies and could not have provided a

reasonable basis for X-11 advertising claims made prior to their publication. However, like the Silverman study, Dr. Hoebel's work would bear upon the propriety of an order in this proceeding if it did, in fact, support respondents' advertising claims.

112. Both of Dr. Hoebel's studies were published "under the auspices of the Brain Research Instruments Company," Dr. Hoebel's private consulting firm (RX 1, p. 192, note 2 and RX 2, p. 200, note 2). The University of Princeton had no connection with either of them and they were not submitted to or reviewed by [65] any of Princeton's faculty committees (Dr. Drenick, Tr. 387-88; Dr. Hoebel, Tr. 1262). In this connection, Dr. Drenick testified (Tr. 387-88):

. . .I have never before seen a publication in medical literature where the author under his credit lines has to state or states that this study was not performed under the auspices of the Investigators [sic] Institution. Dr. Hoebel is a member of the faculty of the Department of Psychology of Princeton University and he prints a statement on Page 192 which says, "This study was performed under the auspices of the Brain Research Instruments Company, 207 Hartley Avenue, Princeton, with support from the Alleghany Pharmacal Corp. of New York, New York, and not Princeton University nor the Medical Center at Princeton," which indicates to me that his institution and the Medical Center associated with Princeton University did not sanction or approve of this article.

113. Alleghany Pharmacal Company and respondent Porter & Dietsch have provided financial support for Dr. Hoebel's work with phenylpropanolamine. Dr. Hoebel had contacted each of these firms and sought financial support. Alleghany Pharmacal, as already noted, markets "Hungrex," a diet pill containing phenylpropanolamine in the same dosage as X-11 tablets (Tr. 1293; see also, CX 123). After Dr. Hoebel had been doing research with phenylpropanolamine on rats for several years, he saw "Hungrex" pills on sale in a drug store and testified that he (Tr. 1179): [66]

. . .got the name of the company off the books [boxes], called them up and suggested they should be supporting our research and, in fact, they did. This was the Alleghany Pharmacal Company. They gave a grant to Princeton University to continue this work with animals.

They also contacted me later and asked if I would be interested in running a study to test the efficacy of this drug in human beings.

On February 10, 1974, Dr. Hoebel wrote to Alleghany over the letterhead of his company, Brain Research Instruments Co., seeking additional funds stating that (CX 209):

Considering that Alleghany's future all hinges on F.D.A. decisions, my publication of the Brain Research Instruments Co. and Princeton University reports is the best buy in advertising you have.

Dr. Hoebel's study results on phenylpropanolamine have been used by "Alleghany Pharmacal in their advertising" (Tr. 1299).

114. Dr. Hoebel's research has also been supported by respondents in this proceeding, Porter & Dietsch. After the complaint issued in this matter, Dr. Hoebel was introduced to individual respondent William H. Fraser, president of Porter & Dietsch. Dr. Hoebel later contacted Porter & Dietsch and suggested that that firm support his research. Dr. Hoebel testified (Tr. 1288): [67]

Q. When did you begin conducting a study for Porter and Dietsch, or when were arrangements made for you to conduct such a study?

A. This fall [1975]. Well, more specifically, when this case came up, and I was introduced to Mr. Fraser of Porter and Dietsch.

My parents live in Minnesota, in St. Paul, so when I visited them, I went to visit him and asked him if he would like to support research at Princeton University, and he said yes. He has.

With respect to his letter to Alleghany Pharmacal Company, Dr. Hoebel testified (Tr. 1291):

It is my opinion that anyone that is selling a drug for human use has a responsibility to support research on that product.

The grant from Porter & Dietsch or Mr. Fraser, although in name to Princeton University, is specifically earmarked for Dr. Hoebel's research (Dr. Hoebel, Tr. 1290).

115. The first study of Dr. Hoebel, "Appetite Suppression By Phenylpropanolamine In Humans" (RX 1), involved a "double-blind" experiment in which test subjects were given either a placebo or a pill containing phenylpropanolamine 30 minutes before being instructed to begin a lunch of Metrecal. The amount of Metrecal ingested at each lunchtime session was measured. In the initial phase of the experiment the test subjects were told by Dr. Hoebel that the purpose [68] was to test the effect of a drug on food intake, and that the subjects would be paid. After a number of procedural refinements were introduced, a difference of 38 cubic centimeters was found between the mean noontime intake of 669 cc's Metrecal for subjects on phenylpropanolamine and 707 cc's for those on the placebo (RX 1, p. 195). Dr. Hoebel reported that "phenylpropanolamine can decrease meal size in a selected population such as we sampled when they are instructed to use the drug according to the instructions given when sold over the counter" (RX 1, p. 196).

116. In evaluating this study, Dr. Margen testified that he disagreed with the statistical methodology employed in reporting

test results. He wrote on the paper when studying it that the statistical methodology was "rigged," and testified (Tr. 179):

. . . as far as the paper is concerned I cannot utilize the data and find that I can come up with any of the conclusions which the author did . . .

Use of a "mean" without any mention of individual variability of food intake was, in Dr. Margen's opinion, a serious defect since any individual differences in a test of this type would be highly significant (Tr. 180-81). Additionally, when further refinements were made in the experimental design by Dr. Hoebel, absolutely no difference in Metrecal consumption was reported and Dr. Margen therefore concluded that "in this paper I cannot find that there is any significant demonstration of the effectiveness of PPA" (Tr. 184). Dr. Margen concluded (Tr. 184): [69]

So here you have a paper which is published without any consideration to variability, and I don't see that the variability was handled in the entire matter of statistics or statistical analyses, and you come up with a very inconclusive thing.

See generally, Dr. Margen (Tr. 174-85).

117. Dr. Drenick also analyzed Dr. Hoebel's first study (RX 1). When asked if this study indicated that phenylpropanolamine is an effective appetite suppressant in humans, Dr. Drenick testified (Tr. 374-75):

I don't think that this article proves that at all, and the reason for my opinion is as follows: Dr. Hoebel treated three groups of subjects. To one group he gave phenylpropanolamine. To another group he gave a placebo but told them that they were going to test the effect of a drug on food intake and weight reduction and he also promised them $15 for participating to be paid at the end of the testing. Therefore, for these two groups he introduced the bias which I have explained to you before. One must not provide that if one wants to have an objective assessment.

In the third group of 32 subjects he stated that he was giving this medication which was a nasal decongestant and to his surprise, when he did that, the [70] patients did not lose any weight and did not reduce their food intake. To my interpretation and assessment this is the only valid group because they did not know that they were supposed to have a weight loss.

Therefore, his conclusion that it was effective in reducing food intake I think is totally in error. The only objective assessment is in the group which did not know what they were getting and there, in fact, he found no effect. So my conclusions differ from his, and I think his are wrong.

118. Dr. Hoebel's second paper, "Body Weight Decreased In Humans By Phenylpropanolamine Taken Before Meals" (RX 2), reported the results of a double-blind, subject-crossover study also designed to investigate the effectiveness of phenylpropanolamine in

appetite suppression and weight control. A weight loss associated with phenylpropanolamine of a fraction of a pound per week during the 4-week period of the study was reported (RX 2, p. 203), and the paper concluded that "phenylpropanolamine was effective in producing a short-term weight loss in the population sampled" (RX 2, p. 206).

119. After analyzing this study Dr. Margen stated that the fractions of a pound of weight loss Dr. Hoebel reported to be associated with phenylpropanolamine may, in fact, have been the result of entirely different stimuli. Dr. Margen testified (Tr. 189-90): [71]

. . . if you look at the percent weight change in two weeks, in the case of the drug it is minus 1.2 percent and in the PPA a difference of 5 percent, and we know the body weight can vary without any treatment over two weeks by that amount.

But I want to point out that even more interesting, and I think this is really a very fascinating part, before the subjects entered the study they were weighed and then they entered the study and in both cases, in the PPA and in the placebo group, there was a significant weight loss in the few days before the study was undertaken, before anything was given. In fact, the weight loss in the patients who were then given the PPA was greater than the weight loss of the people given the placebo and, in fact, the weight loss in the few days in the group given the PPA was, as I calculated it here, about 1.3 pounds, which was as great as the change in over two weeks of the placebo week, so just in anticipation of the experiment the patients lost almost the same amount of weight. It had nothing to do with the administration of anything.

Dr. Margen also noted that, again, only the "means" were reported and no mention was made of the individual variability of test subjects. The potential effect of this omission was explained by Dr. Margen (Tr. 189): [72]

Now, what are the differences? First of all, Dr. Hoebel, if you look at the chart [RX 2, p. 203], the differences look as if they might be rather impressive. For instance, if you look at the PPA [phenylpropanolamine] versus the placebo on the first two weeks, it looks like the people on the PPA went down more than they did on the placebo and it is true they did go down more. The change in body weight during the first two weeks on the drug was minus 2 pounds, on the placebo minus 1.23 pounds, and we are not told the variability.

Now, one individual, mind you, in that group having, let's say, a weight loss of approximately 10 pounds could completely distort the entire group and tell you absolutely nothing and give you an entirely erroneous impression, so unless you have some idea of the variability or some idea of what the individual weight losses were in there, this is absolutely valueless.

In commenting on the study's reported weight losses, Dr. Margen testified (Tr. 191):

. . . [W]e don't have evidence from this paper that this weight loss was even

statistically significant and certainly, from a clinical point of view, this is totally insignificant.

120. Dr. Drenick likewise questioned whether Dr. Hoebel's test results were valid or had medical significance. He testified (Tr. 385-86): [73]

To decide whether or not it [phenylpropanolamine] is effective one has to answer the question whether or not it has a significant effect from a medical point of view or is significant from the point of view of the patient who wants to lose weight. And, in fact, if one analyzes this article more closely, one can see that the greatest weight loss, regardless of whether any drug or placebo was given, occurred before either of these items was administered. The patients lost either 2-1/2—no, 1-1/2 or 1 pound of weight before they received any kind of treatment. Then, over a two-week period the patients who were given the drug lost less than 2 pounds or less than 1-1/2 pounds.

The difference between the phenylpropanolamine treated group and the placebo treated group, the difference in weight loss was less than 1 pound. If you want to express this in a per cent weight change and the difference between the two groups it is 1/2 of 1 per cent difference in weight change.

. . . . . .

When you, however, ask yourself does a difference of less than one pound between treatment groups mean anything to the patient or to a physician, the answer would be obviously not. This much of a difference would not be noticeable in anyone who is significantly overweight.

[74] Of basic importance, moreover, Dr. Drenick pointed out that Dr. Hoebel had no reason to believe the fraction of a pound a week weight loss he attributed to ingestion of a tablet containing phenylpropanolamine would continue, and that Dr. Hoebel himself recognized this (Tr. 386) when he wrote (RX 2, p. 206):

One shoul ' also be aware that our evidence for a statistically significant weight loss in a two-week period does not mean that this rate of loss would be continued over longer periods. Drug tolerance and a myriad of other physiological and social factors could affect longer term results.

121. Neither of Dr. Hoebel's studies constitutes a reasonable basis for the representations of weight losses held out to the public in respondents' advertisements. Weight losses of a fraction of a pound a week do not support or substantiate advertising of respondents conveying the net impression that prospective purchasers and users of the X-11 tablets would lose large poundages of "ugly fat" amounting to virtually any amount, "5, 10, 25 or more pounds," "83 lbs.," "80 lbs.," "40 lbs.," etc. For the obese or overweight, weight losses of a fraction of a pound a week were clinically trivial and insignificant. Further, as already pointed out, Dr. Hoebel himself concluded that a weight loss in a two-week period did not mean that

this rate of loss would be continued over a longer period because of drug tolerance and other factors (RX 2, p. 206).

122. Little of the evidence introduced in this proceeding related to methylcellulose, the second ingredient in X-11 tablets which allegedly is conducive to weight loss. Methylcellulose, as noted, is a "bulk producer," a non-digestible but harmless bulky material [75] no more effective for the treatment of obesity than the "high-residue, low-calorie diet itself" (CX 92, p. 9). "Bulk producers of the methylcellulose family have no proved anorectic effect" (CX 115). Tests by Dr. Drenick, established that within minutes after ingestion of one-half to one gram of methylcellulose, (which is twenty to forty times the 25 mg in an X-11 tablet), the methylcellulose had passed out of the stomach well into the small intestines with no effect on the appetite (CX 115; Dr. Drenick, Tr. 367).

3. *The X-11 tablet does not contain any "unique" ingredient*

123. Respondents have admitted that phenylpropanolamine is the allegedly "unique" ingredient which they identified or alluded to in their X-11 advertisements (Ans. P&D, ¶9, p. 10; Supp. Adm. P&D, No. 41). They also concede that phenylpropanolamine is not unique to X-11 tablets (Motion to Dismiss, p. 84), but contend that the representation made by them was that phenylpropanolamine is a "unique" pharmacological substance. Respondents' advertisements, however, have the capacity to convey the net impression to members of the public reading them the representation that X-11 tablets were the only preparation available without prescription containing phenylpropanolamine. This conclusion is reinforced by the frequent use of terms such as "Now . . . LABORATORY SCIENCE HAS PERFECTED A TINY TABLET" (CX 8, 14 and 15), "RECENTLY, Laboratory Science has perfected. . ." (CX 46-47 and 49), "Here, at last. . ." (CX 19), which convey the impression that scientific research has developed a new, heretofore unknown, aid to those seeking to lose weight.

124. As hitherto made clear, phenylpropanolamine "is a member of the sympathomimetic amine family," a group of agents related pharmacologically and in their chemical structure (Supp. Adm. P&D, No. 35; CX 92, pp. 5-6; RX 1 and 2; Dr. Prout, Tr. 676). Although there are [76] quantitiative differences, phenylpropanolamine being a weak member of this group, all these amphetamine-like drugs produce the same types of responses, *i.e.*, central stimulant effects, wakefulness and increased mental and physical activity (CX 92, p. 6; RX 14, p. 1; Sorer, Tr. 622). Phenylpropanolamine being considerably less potent than amphetamine, its parent

compound (Dr. Prout, Tr. 708), has fewer side effects than other members of the amphetamine family. Because it produces less central nervous stimulation and is the only drug of this class available without prescription, phenylpropanolamine was described as "unique" (Palmer, Tr. 562; Hoebel, Tr. 1201-02). However, considering the representation of "uniqueness" in respondents' advertisements, it is unlikely that the public would interpret this representation to mean only that phenylpropanolamine is unique with reference to other sympathomimetic amines or other pharmacological substances. On the contrary, the representation that respondents' advertisements had the capacity to convey is that, when compared to other dietary aids available without prescription, X-11 tablets contain a totally different or "unique" chemical, in other words, that phenylpropanolamine is unique to X-11 tablets. Since phenylpropanolamine is in many over-the-counter preparations (Dr. Sorer, Tr. 641-42; Supp. Adm. P&D, Nos. 42 and 43; Adm. P&S, No. 42), this representation is false. Respondents have therefore misrepresented in their advertisements that X-11 tablets contain a unique ingredient.

RESPONDENTS' FAILURE TO DISCLOSE MATERIAL FACTS IN ADVERTISING X-11 TABLETS

1. *Respondents failed to disclose that testimonials reciting weight losses of great magnitude did not reflect the typical or ordinary experience of x-11 users*

125. Respondents' advertisements contain a number of testimonials reciting great weight losses achieved by users of X-11 tablets. For example, in CX 19, as [77] discussed in earlier findings, Mrs. George Stowe, Canon, Georgia, is quoted "I USED TO WEIGH 160 LBS. NOW I'M DOWN TO 105", Mrs. Ken Schmidt, Norfolk, Nebraska, is pictured stating "I LOST OVER 40 LBS., TOO," and Mrs. Beverly Tellier, Chula Vista, California, likewise is shown stating "I LOST OVER 40 LBS." In another ad Mrs. Ken Schmidt is quoted "I LOST 80 LBS!" (CX 18). The record is replete with similar testimonials (see, *e.g.*, CX 1, 2, 15, 22, 24, 44, 49 and 68).

126. Through the use of such testimonials respondents represented that the results obtained by those giving testimonials reflected the typical or ordinary experience of persons purchasing and using X-11 tablets. In the testimonials the least amount of weight loss claimed is 40 pounds (CX 19), and the claims range as high as 83 pounds (CX 68). Multiple testimonials were often used in the same advertisement adding to the implication that it is typical for users of

X-11 tablets to experience weight losses of such magnitudes. Statements such as "FROM GEORGIA TO NEBRASKA TO CALIFORNIA American Women Have Found A Way That Really Helps Off THAT UGLY FAT" (CX 1 and 19) also reinforced the implication that the stated weight losses were typical for all users of X-11 tablets.

127. The weight losses cited in the testimonials in respondents' advertisements, however, are not representative of the typical or ordinary experience of purchasers and users of X-11 tablets. The tablets themselves produce no weight loss and medical experience establishes that even with a stringent dietary regime, and professional supervision, weight losses of the magnitudes portrayed by respondents' testimonials are highly unusual and extraordinary for overweight or obese individuals.

128. Dr. Prout testified that only one in twenty patients instructed in a weight-reducing regimen would achieve weight losses of twenty to thirty pounds within [78] a period of approximately twenty weeks (Tr. 717). Dr. Drenick testified that "[o]nly ten percent of obese individuals will ever lose more than 40 pounds in a single dietary regimen" (Tr. 412). In *Drugs of Choice* (CX 92), Drs. Modell and Reader stated that "most obese patients will not stay in treatment," and "of those who do, most will not lose weight" (CX 92, p. 2).

129. Based on the above statements, it is apparent that a weight loss of 40 to 83 pounds for an obese individual would be extremely rare. Respondents have failed to disclose to potential users of X-11 tablets the fact that, contrary to the results achieved by those whose testimonials are published, weight losses of great magnitude are not representative of the typical or ordinary experience of X-11 users.

2. Respondents failed to disclose in their advertisements for X-11 tablets that persons with high blood pressure, heart disease, diabetes or thyroid disease should use X-11 tablets only under the direction of a physician

130. Respondents Porter & Dietsch, William H. Fraser, Kelly Ketting Furth and Joseph Furth admitted that phenylpropanolamine, because of its pressor effect, should not be ingested by persons with high blood pressure, heart disease, diabetes or thyroid disease except under the advice and supervision of a physician (Adm. P&D, No. 59). The package insert accompanying X-11 tablets contains an FDA-required warning that persons with those diseases or conditions should use X-11 tablets only as directed by a physician (Adm. P&D, Nos. 60-61; Adm. P&S, Nos. 60-61). [79] The package containing X-11 tablets also has "CAUTION: Individuals with high blood pressure,

heart disease; diabetes or thyroid disease should use only as directed by a physician. . ." printed on the back (CX 36 and 39). Despite respondents' awareness that X-11 tablets should not be used by such members of the public, they made no mention of this fact in any of the X-11 advertisements.

131. Phenylpropanolamine is an active vasoconstrictor which tends to constrict blood vessels and thereby elevate blood pressure (CX 94; RX 5; Dr. Drenick, Tr. 369-70; Dr. Prout, Tr. 695). For a person already afflicted with high blood pressure, ingestion of phenylpropanolamine could elevate blood pressure to even higher, and possibly dangerous, levels (Dr. Margen, Tr. 238-39); Dr. Drenick, Tr. 417; Dr. Sorer, Tr. 627-28). According to Dr. Sorer, giving a product containing a sympathomimetic amine to an individual with high blood pressure "would be like dousing a fire with gasoline" (Tr. 627).

132. Phenylpropanolamine can also be dangerous to a person with heart disease by putting an extra strain on his or her heart, with potentially serious consequences (Dr. Drenick, Tr. 417-18); Dr. Sorer, Tr. 629-30). Dr. Sorer testified (Tr. 629):

> We are talking about people with low cardiac reserve where an extra weight placed on the heart or its organism could prove fatal or adverse.

Such danger would be greater for a person on a nutritionally deficient diet such as that contained in the X-11 package, because this makes a person's nervous system even more susceptible to the irritant effects of phenylpropanolamine (Dr. Drenick, Tr. 417). [80]

133. Large numbers of the nation's public have high blood pressure or heart disease. Data of the National Center for Health Statistics of the U.S. Public Health Service, reported by the American Heart Association, show that, as of 1972, an estimated 28,410,000 Americans have either high blood pressure or some form of heart disease. Of these, some 22,950,000 — or one of every six adults — have high blood pressure (CX 109, pp. 13, 29). Although half of the people with high blood pressure are not aware that they have this condition (CX 109, pp. 13, 29), an admonition in advertisements against use of X-11 tablets by individuals with high blood pressure or heart disease would serve to notify a large number of potential purchasers that they should not use, or purchase, X-11 tablets.

134. For persons with diabetes, phenylpropanolamine carries the risk of elevating the blood glucose level, thus aggravating a situation already potentially hazardous. Dr. Sorer testified (Tr. 630):

> On pharmacological grounds, again these agents do elevate blood glucose. Diabetics

have already elevated blood glucose very simplistically so this could again make a potentially bad situation worse. It is possible.

135. According to the official Report of the National Commission on Diabetes, dated December 1975, diabetes is increasing by 6 percent each year, and now affects one out of every 20 Americans (CX 108, p. 1). Dr. Prout, whose expertise includes diabetes treatment, feels that these figures are conservative and that the true rates of increase are even higher (Tr. 701-02). Dr. Fineberg characterizes the increase in diabetes as "exploding" (Tr. 1360-61). The likelihood of being diabetic doubles with every decade of life, and more than doubles with every 20 percent of excess weight (CX 108, pp. 2, 47; Dr. Prout, Tr. 703), and 70 to 85 percent of all adult diabetics are over-weight [81] (CX 108, p. 15; Dr. Prout, Tr. 703). These figures establish the need for a warning in respondents' advertisements against use of X-11 tablets by a substantial portion of the purchasing public who should not ingest any product containing phenylpropanolamine.

136. High blood pressure, heart disease and diabetes occur more frequently and with greater severity among the obese and overweight than in the population generally (Adm. P&D, No. 53; Dr. Prout, Tr. 702; Dr. Margen, Tr. 151).

137. Persons with overactive thyroid also subject themselves to increased health hazards by ingesting phenylpropanolamine. Dr. Drenick testified (Tr. 418):

Q. If a person with thyroid disease took X-11 tablets together with the instructions [sic] for their use, would that result in a danger for that person?

A. If the thyroid were overactive, I think it would. . . .

Q. Should . . . persons with . . . thyroid disease use such a preparation as X-11 only as directed by a physician?

A. Yes.

138. First-time purchasers of X-11 tablets through the mails plainly have no way of knowing, and obviously are unaware at the time of purchase, of the warning on the package of X-11 tablets. (Adm. P&D, No. 62; Adm. P&S, No. 62). Also, the public may rely [82] entirely on the affirmative representations in respondents' advertisements and fail to notice the limitation as to use printed on the back of the X-11 package prior to purchase.

139. The potentially hazardous consequences to the health of overweight or obese persons who have high blood pressure, heart disease, diabetes or thyroid disease from ingestion of X-11 tablets,

are material facts of the greatest importance, and plainly had the capacity to affect the consideration by such persons of whether or not to purchase respondents' tablets.

3. *Respondents failed to disclose in advertising that a highly restricted caloric diet is an integral adjunct to the use of X-11 tablets*

140. As is clear from what has already been said, for users of X-11 tablets to lose weight, a "diet" must be followed and caloric intake must be restricted (Dr. Drenick, Tr. 350; Carretta, Tr. 661). The package of X-11 tablets, as noted, contains instructions and a diet providing for a drastic reduction of caloric intake (CX 37, 40 and 133), and expert testimony described this as a "starvation" or "semi-starvation" diet (Dr. Margen, Tr. 169; Dr. Drenick, Tr. 406; Dr. Fineberg, Tr. 1330). Respondents' advertisements, however, failed to disclose that, in conjunction with the use of X-11 tablets, a severely restricted diet had to be followed. On the contrary, the public was told that they could continue to "EAT" and "EAT WELL" while losing "ugly fat." Failure to disclose that a highly restricted, low-caloric diet had to be followed for purchasers and users of X-11 tablets to lose weight constituted a failure to disclose a material fact likely to affect the decision of members of the public whether or not to purchase X-11 tablets. [83]

RESPONSIBILITY OF WILLIAM H. FRASER FOR DECEPTIVE ADVERTISING OF X-11 TABLETS

141. As stated at the beginning of this decision, individual respondent William H. Fraser is the president and sole owner of Porter & Dietsch (Fraser, Tr. 753-54). Admittedly, he formulates, directs and controls the acts and practices of Porter & Dietsch (Ans. P&D, ¶1).

142. Mr. Fraser's responsibility for the deceptive advertising of X-11 tablets does not, however, derive solely from his role as the chief executive officer and owner of respondent Porter & Dietsch. He was an active participant in the formulation and dissemination of the advertising here in issue. Although stating he relied entirely on Mr. Gettleman for the X-11 tablet advertising content (Tr. 798 and 878-80), Mr. Fraser, in fact, originated the use of testimonials (Furth, Tr. 962-63), and made other contributions to the advertising content (Furth, Tr. 977-78). He discussed X-11 advertising with Mr. Furth, who subsequently met with Mr. Gettleman to complete the ad copy (Fraser, Tr. 797; Furth, Tr. 959). Mr. Fraser, furthermore, had

the power to reject advertisement ideas developed by Mr. Furth and Mr. Gettleman (Fraser, Tr. 798). When advertisements were completed in final form, Mr. Fraser handled their preparation for dissemination (Fraser, Tr. 796), and thereafter placed them directly or sent authorizations to retailers for ad placement (Fraser, Tr. 795 and 799). Mr. Fraser is responsible for the X-11 advertisements as chief executive officer and sole owner of Porter & Dietsch, and as an active participant in their creation and dissemination.

RESPONSIBILITY OF KELLY KETTING FURTH AND JOSEPH FURTH FOR DECEPTIVE ADVERTISING OF X-11 TABLETS

143. Respondent advertising agency Kelly Ketting Furth and individual respondent Joseph Furth played an active role in the misleading and deceptive advertisements [84] disseminated by respondents Porter & Dietsch and William H. Fraser. Mr. Furth began work on the advertising of X-11 tablets for Porter & Dietsch in June 1968, two or three weeks before the formation of Kelly Ketting Furth (Furth, Tr. 928-35; CX 83). After Kelly Ketting Furth commenced business, Mr. Furth summarizes the firm's role as the advertising agency for Porter & Dietsch as follows (Tr. 927):

> An advertising agency functions with an advertiser in the liaison preparation of, development of, placing of advertising.

Joseph Furth was the account executive in Kelly Ketting Furth responsible for the Porter & Dietsch account, and prepared advertising copy for products marketed by Porter & Dietsch (Ans. P&D, ¶4). His function as account executive was ". . . to handle it in a normal way in which an advertising agency might handle the advertising for an advertising client" (Tr. 937). During the time he has been Kelly Ketting Furth's account executive for Porter & Dietsch, Joseph Furth has implemented and prepared all advertising copy for the X-11 tablets (Fraser, Tr. 794-98; Furth, Tr. 944-46; Adm. P&D, No. 10 b and 3).

144. In addition to implementing and preparing advertising copy, Mr. Furth originated the theme which pervaded respondents' X-11 advertising in one form or another: "Eat Well and Lose [That] Fat." Mr. Furth testified that his suggestion to Mr. Gettleman developed into this advertising concept and was used in the "first original conventional newspaper advertisement" (Tr. 981-82). This slogan appeared in an X-11 advertisement as early as 1969 (CX 87). Mr. Furth and Mr. Gettleman worked together in creating and developing subsequent X-11 advertising (Tr. 951 and 956). [85]

145. Kelly Ketting Furth and Mr. Furth put the ideas and

suggestions of Mr. Gettleman into finished advertisements, establishing emphasis, headlines and layout (Tr. 940-41, 958-61 and 964-65). In short, they played an active role. A letter to Mr. Fraser from Kelly Ketting Furth by Mr. Furth, vice-president, dated September 13, 1968, reads (CX 151): "Enclosed is suggested copy and layout for ad you requested for newspaper weeklies." On November 1, 1968, Mr. Furth wrote to Mr. Fraser (CX 152):

> About two months ago, on your request, I prepared a 35-line ad on X-11, and sent it to you.
>
> . . . . . .
>
> This could be an effective way to get a steady bleed on Free Standing Stuffer markets.

Again on December 4, 1968, Mr. Furth wrote to Mr. Fraser (CX 153):

> I am enclosing layout for a revised format for the Free Standing Stuffer.
>
> I believe that it has a "nicer feel," yet retains the power of the previous insert.
>
> *On the Imprint side* we have used a more meaningful illustration of a slim doll, who appears to be anticipating the food she has ordered. It graphically gets over the point, "Eat what you want and slim down." [86]
>
> On this side, I would like to use the copy we used previously.
>
> We have reversed the panel on the flap from red to blue — and I think it looks stronger.
>
> *On the back side* I wanted to retain the "power" of our previous insert, but have changed the headline to that of our 16" dealer ad which seems to be perking. Here, I would intermix copy from the dealer ad with some of the copy now in the stuffer. I would like to keep the copy as is in the pink panel.
>
> We have made provision for the weight chart in the lower panel.
>
> What do you think? Should we switch over perhaps in February?

146. Mr. Furth kept Mr. Fraser up to date on X-11 advertising developments (CX 154-55). In a letter of January 28, 1971, Kelly Ketting Furth and Mr. Furth advised Mr. Fraser of Mr. Gettleman's "approval on copy" for an X-11 advertisement, Mr. Furth stating that he would work Mr. Gettleman's idea in "as follows" providing Mr. Fraser with proposed copy (CX 156). In another letter dated July 14, 1971, Mr. Furth wrote Mr. Fraser "I am returning the Odrinex copy, and copy I have prepared patterned on the small ad all type format" (CX 157). "Odrinex" is a "diet pill" competing with X-11 tablets (CX 157, p. 3). In letters of August 29 and December 4, 1972, Mr. Furth made suggestions to Porter & Dietsch relating to the

testimonials in the X-11 advertisements of Mrs. Stowe, Mrs. Tellier and Mrs. Schmidt, and the layout of other features (CX 159 and 160). On June 18, 1973, Mr. Furth sent Mr. Fraser a "second 2-column newspaper ad" noting that it was [87] "virtually resized from the page Roto ad which ran over Drug Guild's name in the New York News and did so splendidly," and that "it basically is our original ad, done a little differently, and the ad that Thompson 'swiped' for Appedrine" (CX 162). The advertisement featured "Eat Well. . .And Lose That Fat" picturing an X-11 tablet and a silhouette of a slim lady (CX 162, p. 2). On July 13, 1973, Mr. Furth sent Mr. Fraser an X-11 advertisement cast in the "Standard [R]oto size" suitable for the "Minneapolis Sunday Roto" (CX 163). This advertisement contained handwritten revisions on the Kelly Ketting Furth letterhead. On October 31, 1973, Mr. Furth wrote Mr. Fraser (CX 165):

> You've asked for "new" ads. I've been holding out for the old.
>
> Here is a compromise that has some new elements the competition is not yet using.
>
> First, Appedrine and now Odrinex have adopted our silhouette figure. I don't want to drop ours. But I have added a reduced "pot-bellied" man to indicate how much "gut" he has taken off. This may give us the man-and-woman appeal, which the others aren't using.

(See also CX 166 through CX 173).

147. On March 14, 1974, Mr. Furth advised Porter & Dietsch against a suggestion for affixing "a pressure sensitive sticker on the X-11 package stating 'Does not contain amphetamines' ", a proposal advanced to counter newspaper publicity linking Hodgkin's disease with the use of diet pills containing "amphetamines or related drugs" (CX 168). He commented to Mr. Fraser that the idea "should be viewed cautiously" because phenylpropanolamine "is a 'cousin' related structurally and pharmacologically" to amphetamine, and that since [88] "[w]e are dealing with 'Label' as differentiated from advertising. . .we would be a 'sucker' for possible FDA misbranding, hence seizure" (CX 168).

148. Kelly Ketting Furth and Joseph Furth handled the placing of Porter & Dietsch's X-11 advertising in publications throughout the country (Stipulations, Tr. 378-83; Fraser, Tr. 881; and Furth, Tr. 942-43). Advertisements in media which recognize "national" advertisers as a rate class, such as *TV Guide*, were placed for Porter & Dietsch by Kelly Ketting Furth by forwarding them directly to the publication. Kelly Ketting Furth was then billed for such space (Furth, Tr. 942-43; Stipulation, Tr. 381-83). "National" advertising

accounted for about half of all advertising of X-11 tablets (Fraser, Tr. 868).

149(a). Kelly Ketting Furth, and individual respondent Joseph Furth, played an active role in the creation and dissemination of Porter & Dietsch's advertising for X-11 tablets, and knew or should have known that the representations contained in such advertising were false, misleading and deceptive. That this is true is not only revealed by the facts set out in the foregoing findings, but is dramatically shown by the letter from Mr. Furth to Mr. Fraser (CX 164), quoted earlier in this decision, in which he answered Mr. Fraser's criticism that an advertisement for the X-11 tablets lacked "punch." Mr. Furth displayed his keen knowledge of the X-11 tablet advertising, both content and strategy, and his active role in creating and disseminating it, by commenting to Mr. Fraser on the dangers of "put[ting] emphasis on the tablets" in making weight loss claims—"That's murder, because the pills will not reduce weight an iota" (CX 164). Mr. Furth continued in his letter warning Mr. Fraser against putting in the advertisements for X-11 tablets the same kind of "punch" used in the competing "diet" pill advertising of Appedrine, Hungrex and Odrinex, [89] noting frankly that he was afraid "we're all going to get into hot water because of Appedrine, Hungrex and Odrinex" (CX 164, p. 2).

RESPONSIBILITY OF PAY'N SAVE CORPORATION FOR THE DECEPTIVE ADVERTISING OF X-11 TABLETS

149(b). Pursuant to arrangements with Porter & Dietsch, many advertisements for X-11 tablets were placed for publication by officials of Pay'n Save Corporation over the Pay'n Save corporate name. Pay'n Save lent its name, prestige and corporate identity to the advertisements for X-11 tablets, and the claims and representations made for them in such advertisements thus became those of Pay'n Save Corporation.

150. The working arrangement between Porter & Dietsch and Pay'n Save Corporation originated around 1969 or 1970. A representative of Porter & Dietsch persuaded the manager of the Everett, Washington, store of Pay'n Save to put in a stock of X-11 tablets and to run an advertisement (Palmer, Tr. 507-08; Affidavit of Calvin Hendricks attached to Motion to Dismiss of Pay'n Save dated November 28, and filed December 1, 1975). The promotion was successful and the Pay'n Save buying committee decided to advertise X-11 tablets throughout the Seattle area. Thereafter, Pay'n Save drug stores generally carried and advertised the X-11 tablets (Tr. 508-13). The criteria used by the Pay'n Save buying committee in

deciding to carry and advertise X-11 tablets, according to Pay'n Save's pharmacy supervisor, was that (Palmer, Tr. 513): [90]

> They [Everett Pay'n Save store] had sold a hundred-plus units of product in a three-day ad, which is considered very good return on a brand new item, and so, based on this, they [the buying committee] were looking for something that might be successful in all stores. If we could sell a hundred of everything brand new the first time we advertised it, we would be very happy.

The decision of the buying committee was based entirely on the successful sales generated in the Everett store, and the claims and representations contained in the advertisements to which Pay'n Save lent its name were not scrutinized (Palmer, Tr. 510-14).

151. Under the arrangement between Pay'n Save and Porter & Dietsch, the dates and media in which X-11 advertisements were published were selected by Porter & Dietsch, and insertion orders were sent by that respondent to Pay'n Save. The latter paid the publication for carrying the advertisements and was later reimbursed for between 75 and 90 percent of the cost by Porter & Dietsch upon transmittal of a tear sheet. In such instances, the X-11 tablets were advertised, and all the claims and representations described and set out in earlier findings, were made over the name of Pay'n Save Corporation (see Stipulations Tr. 115-17, 377-80, 428-35; Affidavit of Calvin Hendricks, *supra;* RX 8 through 13; Palmer, Tr. 518-26). Readers and prospective purchasers were told that the X-11 tablets were available at all Pay'n Save stores. A coupon was also attached to many of the advertisements for prospective purchasers to fill out and mail to Pay'n Save Corporation to receive a supply of X-11 tablets by mail (CX 1-2, 14-20, 29, 31-33, and 35). In other words, respondent Pay'n Save Corporation advertised the X-11 tablets as if the tablets were its own product. [91]

152. Wherever advertisements for X-11 tablets appeared over the Pay'n Save corporate name, it was with the approval and by the direction of Pay'n Save (Tr. 525). At all times, Pay'n Save Corporation had the option of accepting or rejecting the X-11 advertisements submitted to it by Porter & Dietsch (Fraser, Tr. 807). However, as indicated, such advertisements were neither analyzed nor evaluated by Pay'n Save prior to its decision to publish them (Palmer, Tr. 510-14).

153. Porter & Dietsch was never contacted by Pay'n Save Corporation for material substantiating the claims and representations for the X-11 tablets made in the advertisements, nor to determine if Porter & Dietsch had such material, and Pay'n Save had no information whatever as to whether there was any reasonable basis for such claims and representations (Palmer, Tr. 547-50, 471-72). Nor did Pay'n Save officials, or its pharmacy supervisor, make any inquiry of their own. In sum, Pay'n Save depended totally upon Porter & Dietsch, as follows (Tr. 547):

> I think we were depending totally upon the manufacturer to present a product that had been sold and advertised to other people for a number of years and that upon that basis we felt that apparently the product did have merit.

Pay'n Save Corporation thus published advertisements over its own name making affirmative claims and representations to the public for the X-11 tablets without knowing whether or not those claims and representations were true or false, without having made any inquiry to determine whether they were true or false, and without knowing or having made any inquiry to determine whether there was even a reasonable basis for such claims and representations. [92]

154. Under the circumstances, Pay'n Save Corporation is, and must be, responsible for the deceptive representations made to the public. Pay'n Save is not relieved from such responsibility because the content and copy of the advertisements were prepared and created by the other respondents in this proceeding.

III

Basic Considerations

1. Tablets

Respondents Porter & Dietsch, William H. Fraser, Kelly Ketting Furth and Joseph Furth place great emphasis upon the contention that they advertised and marketed a "plan," not tablets and therefore made no representations as to the X-11 tablets alone. As the findings disclose, this argument is unsubstantiated by the facts and is rejected. An examination of respondents' many advertisements, in the opinion of the law judge, demonstrates beyond question that respondents were promoting and selling X-11 diet tablets, and that the representations made to the public in respondents' advertisements related to the efficacy of the tablets and the results to be achieved from their use.

Labeling the box of tablets the "X-11 Reducing Plan," coupled with the liberal use in advertising copy of the word "plan," does not and cannot change the realities of respondents' product. Repeated use of the word "plan" in the advertisements and on the box of X-11 tablets was, in the view of the law judge, a transparent attempt to avoid what respondents accurately perceived to be dangers in [93] making significant, large weight reducing claims of virtually any amount for the tablets. As reiterated herein, Porter & Dietsch's

advertising account executive, individual respondent Joseph Furth, revealed the true reason for respondents' effort to transform the advertising and sale of X-11 tablets into the promotion of a reducing "plan" (CX 164):

> Appedrine and Hungrex (even Odrinex) put emphasis on the tablets. That's murder, because the pills will not reduce weight an iota.
>
> It is the "Plan" that will keep us out of hot water.

The genesis of respondents' claim to be marketing a "plan" undoubtedly lies in *Carlay Co.* v. *Federal Trade Commission*, 153 F.2d 493 (7th Cir. 1946), where a Commission order against a candy product presented as a reducing aid was overturned, and the court accepted the argument that a "plan" was involved. But *Carlay* does not decide the factual issue of what respondents were, and are, marketing in this proceeding.

The Commission has had occasion in recent years to deal with cases where contentions were made that a "plan" rather than an individual product was being advertised and sold.

In *Stauffer Laboratories, Inc.*, 64 F.T.C. 629 (1964), a "Magic Couch" was marketed as part of a home reducing "plan" to "lose unwanted pounds." Respondents in that proceeding contended that their couch was sold only as an "inextricable integral [94] component" of the Stauffer "plan," and that it was erroneous to construe representations in their advertising as applicable only to the "Magic Couch." Many of the advertising claims in *Stauffer* resemble those of respondents here. (See 64 F.T.C. at 646.) The Commission concluded that, notwithstanding repeated references to "plan," claims were made for the "Magic Couch" independent of the "plan." The Commission concluded (64 F.T.C. at 648):

> We fail to see merit in respondents' urging that a "plan" is involved. As stated above, the device was represented as being effective of itself, and the challenge is made to that claim. Moreover, the "plan" is in reality nothing more than the device served with a little garnish of advice and handholding.

On appeal, *Stauffer Laboratories, Inc.* v. *Federal Trade Commission*, 343 F.2d 75 (9th Cir. 1965), respondent *Stauffer* relied on the *Carlay* case and charged the Commission with error in finding that members of the public were misled into believing that claims made for the "plan" related solely to the couch. *Stauffer* argued to the Court of Appeals that (343 F.2d at 78):

> . . .Petitioner advertises and sells a "Stauffer Home Plan," a "Stauffer Home Reducing Plan," a "Figure-Beautifying Plan," and a "Stauffer Principle" of "sensible" weight reduction and muscle toning. All of these terms are constantly used in Petitioner's advertising and booklets.

[95] The Ninth Circuit rejected this argument and affirmed the Commission's decision, without even citing *Carlay*, noting that in working out its selling program *Stauffer* undertook to tie the couch in with a "plan" consisting of a diet and couch, because the device was the money making part of the operation whereas (343 F.2d at 78):

> Low calorie diets can be readily procured in small, inexpensive booklets or pamphlets; they can be procured without charge or for a nominal sum from the Government Printing Office, and they may be found in almost any ladies' magazine.

In the present proceeding respondents' claim to be promoting a "plan" is likewise grounded on the insertion in the box of X-11 tablets of a single-page leaflet containing a low-calorie diet (CX 37 and 40).

In *Damar Products, Inc.*, 59 F.T.C. 1263 (1961), respondents marketed a "Salon Vibrator Plan" for helping "to achieve the slimmer figure you have often admired." The Commission adopted the then hearing examiner's decision finding that respondents' advertisements had the effect of causing members of the public to believe that the claims of "body-weight reduction" related to the "vibrator" alone even though the *Damar* advertisements referred to a "plan." The Court of Appeals affirmed. *Damar Products, Inc.* v. *Federal Trade Commission*, 309 F.2d 323 (3rd Cir. 1962).

As it was in the foregoing cases, so it is here. Respondents' use of "plan" in marketing their diet tablets was simply a "gimmick" used in an effort to escape liability for deceptive claims and representations for X-11 tablets. [96]

2. *Representation that users could lose weight without dieting*

Respondents contend that their advertising did not represent that users of X-11 tablets could lose weight without restriction of their caloric intake stating that the ads "speak loudly" that the X-11 tablets will "control your appetite," "counteract hunger," and further contain language such as "you eat less, want less." Respondents, however, ignore the predominant theme of the X-11 advertisements.

Respondents' advertisements, as described in the findings, are replete with emphatic statements and bold-type representations implying that no dieting was required, that users of X-11 tablets could "EAT WELL . . . AND LOSE THAT FAT," "WITHOUT EVER MISSING A

MEAL," could "ENJOY FOODS [THEY] CHOOSE," that users could "SATISFY [THEIR] APPETITE" "WITHOUT EVER GOING HUNGRY," that users could lose weight without "STICKING TO BORING REDUCING DIETS," without "STARVATION DIETING HUNGER," without "HUMDRUM METHODS SO MANY WOMEN HAVE TRIED AND GIVEN UP IN DESPAIR," and many other like promises and representations. The net impression conveyed to the public by respondents' advertisements is what counts. *Charles of the Ritz* v. *Federal Trade Commission*, 143 F.2d 676, 679 (2nd Cir. 1944); *U.S. Retail Credit Ass'n, Inc.* v. *Federal Trade Commission*, 300 F.2d 212, 219 (4th Cir. 1962); *J. B. Williams Co. Inc.*, v. *Federal Trade Commission*, 381 F.2d 884, 889-90 (6th Cir. 1967). Advertisements are to be judged by their effect on the average member of the public who will be influenced by the impression gleaned from a quick glance at the most legible words. *Ward Laboratories, Inc.* v. *Federal Trade Commission*, 276 F.2d 952, 954 (2nd Cir. 1960), *cert. denied*, 364 U.S. 827; see also, Commission decisions of November 26, 1974, in *Standard Oil of California*, CCH Trade Reg. Rep., ¶20,789, page 20,655, and in *Crown Central Petroleum Corp.*, CCH Trade Reg. Rep. ¶26,790, page 20,669. The net impression of [97] respondents' advertisements, as previous findings set out, is that users of X-11 tablets could lose "ugly fat" "without restricting their accustomed caloric intake—in short, without dieting."

3. *Representation of reasonable basis for advertising that substantially all users of X-11 tablets would lose a significant amount of weight*

Respondents insist that even if they are held to have marketed and made representations about tablets rather than a reducing "plan," they did not represent to the public that *substantially all* users of X-11 tablets would lose a significant amount of weight. Respondents' advertisements were directed to the public at large, particularly to the overweight and obese. They held out and represented to the public that significant, large amounts of body weight of virtually any amount, could and would be lost by anyone who purchased and used the X-11 tablets. Such representation was not made to any limited portion of the public, but to every reader of X-11 advertisements. The advertisements contained no limitations, but told all readers "YOU" are offered "a way to get rid of unsightly, superfluous fat you're carrying," a way "to lose 5, 10, 25 or more pounds of unsightly fat," and the like. Results were guaranteed to every reader or "money back." Considering respondents' advertisements in their entirety, such advertisements had the capacity and tendency to lead

members of the public to believe that respondents had a reasonable basis from which to conclude that substantially all X-11 users would lose virtually any amount of weight desired. See *National Dynamics Corp.*, 82 F.T.C. 488, 564 (1973), *aff'd* but remanded as to Paragraphs 1 and 2 of the order, *National Dynamics* v. *Federal Trade Commission*, 492 F.2d 1333 (2nd Cir. 1974), *cert. denied*, 419 U.S. 993. [98]

4. *Failure to have a reasonable basis for representations of a significant weight loss*

Respondents did not have a reasonable basis for their representations of weight loss, either when X-11 tablets were first put on the market and advertised in 1967, during subsequent years, or as a result of more recent studies by respondents' experts, Drs. Silverman and Hoebel.

In support of their claim that they had a reasonable basis for their representations of weight loss respondents rely on the *Alleghany Pharmacal* proceeding, 75 F.T.C. 990 (1969). The evidence in that proceeding most favorable to respondents, however, only supports the proposition that a preponderance of the evidence did not establish that phenylpropanolamine was without "significant pharmacological value as an appetite suppressant or weight reducing agent."

There is, in fact, substantial evidence in this record that phenylpropanolamine is ineffective as an appetite suppressant in the 25 mg dosage contained in each X-11 tablet. But whatever the truth may be in this respect, neither the evidence here nor in *Alleghany Pharmacal* establishes that respondents had a reasonable basis for representing that 25 mg of phenylpropanolamine ingested one-half hour before each meal will bring about the significant, large weight losses of virtually any amount held out to the public in respondents' advertising. As the Commission remarked in *Crown Central Petroleum, supra*, CCH Trade Reg. Rep. at page 20,665:

> respondents' advertising claims greatly exceed even the most favorable interpretation of [the] evidence.

[99] And as the Commission said in *National Dynamics, supra*, 82 F.T.C. at 549:

> A performance claim is not a technique which can be used with impunity for ascribing specific attributes to a product based on nothing more than a guess that it will perform as represented.

In the opinion of the law judge, before respondents could lawfully

hold out to the public in their advertising that users of X-11 tablets would lose virtually any amount of weight—83 lbs., 80 lbs., 55 lbs., 40 lbs., "5, 10, 25 or more" lbs.—respondents were obligated to have available adequate and well-controlled scientific studies or tests providing a valid scientific or medical basis for such claims. The Commission made clear in *Pfizer, Inc.*, 81 F.T.C. 23 (1972), that the type of substantiation required to satisfy the reasonable basis standard would depend on the facts of each case. In this proceeding, respondents were advertising a drug to be taken internally for the treatment of overweight and obesity, which conditions pose serious and real dangers to the health. Under such circumstances, the foregoing standard of substantiation was required. Respondents did not, and do not now, have such substantiation. Indeed, respondents did not even meet a lesser standard. Neither medical literature, clinical experience, nor general medical knowledge provided in 1967, when X-11 tablets were first placed on the market, or now provide, a reasonable basis for the representations of weight loss in respondents' advertising.

5. *Advertising X-11 tablets as containing a unique ingredient was deceptive*

Respondents contend that X-11 tablets contain a "unique" ingredient because phenylpropanolamine differs from other pharmacological substances, and because [100] phenylpropanolamine is the only member of the phenethylamine family sold without a prescription. Respondents' advertisements, however, do not convey this limited meaning for "unique" to the public. It has long been established that in evaluating advertising claims, a technical interpretation of each phrase is not the standard applied to determine deceptiveness. Rather, evaluation of the over-all impression advertisements are likely to make on the buying public determines whether or not such advertisements are deceptive. *Murray Space Shoe Corp.* v. *Federal Trade Commission*, 304 F.2d 270, 272 (2nd Cir. 1962). Purchasers of X-11 tablets could reasonably have concluded that the "unique" claims in respondents' advertisements meant that X-11 tablets were the only dietary aid available over the counter containing phenylpropanolamine.

In finding that respondents' advertising of a "unique" ingredient is deceptive, it is not necessary that a conscious intent to deceive be shown. *Federal Trade Commission* v. *Algoma Lumber Co.*, 291 U.S. 67, 79 (1934); *Koch* v. *Federal Trade Commission*, 206 F.2d 311, 317 (6th Cir. 1953); *Ford Motor Company* v. *Federal Trade Commission*, 120 F. 2d 175, 181 (6th Cir. 1941); *Gimbel Bros., Inc.* v. *Federal Trade*

Commission, 116 F.2d 578 (2nd Cir. 1941). Even if respondents intended to convey only the limited meaning which they now ascribe to "unique," where an advertising claim has dual or multiple meanings, one of which is false, such advertisements are misleading. *Giant Food Inc.* v. *Federal Trade Commission*, 322 F.2d 977, 981 (D.C. Cir. 1963); *cert. dismissed*, 376 U.S. 967 (1964); *Rhodes Pharmacal Co., Inc.* v. *Federal Trade Commission*, 208 F.2d 382, 387 (7th Cir. 1954), *rev'd* in part reinstating Commission decision, 348 U.S. 940 (1955). [101]

6. *Testimonials were deceptive*

Respondents assert that testimonials included in their advertisements were not deceptive since these testimonials "relate specifically to the 'plan' and do not relate to the tablets at all" (Motion to Dismiss, p. 89). The contention relating to the "plan" has been discussed in detail and rejected. It is worth noting again, nevertheless, that as their original letters disclose (CX 147-49), persons whose testimonials were used looked upon respondents' product as tablets, not a "plan." In publishing the testimonials, the endorsements of "tablets" or "diet pills" in the original letters from X-11 users were changed to refer to the "X-11 Plan" or "X-11 Reducing Plan."

When an advertisement contains a testimonial reflecting the experience of an individual with a product, there is an implicit representation that such experience reflects the typical or ordinary results anyone may anticipate from use of the product. *National Dynamics Corp., supra* at 564. The weight losses publicized in testimonials in respondents' advertisements do not reflect the typical or ordinary experience of users of X-11 tablets, or the results overweight or obese persons can typically anticipate from their use. Following a low-calorie diet is very difficult, especially for the seriously obese and overweight and is seldom successful (see, for example, CX 92-93, 96 and Dr. Drenick, Tr. 406), although on occasion, of course, someone will persevere and lose a large amount of weight.

The argument of respondents' (Motion to Dismiss, p. 91) that a testimonial to a weight loss of 83 lbs. is only relevant to someone who is 83 lbs. or more overweight is fallacious. As complaint counsel correctly point out, someone who is 25 pounds overweight will reason that if X-11 tablets will cause a person 83 lbs. overweight to lose that amount of excess fat, they will surely be effective to cause a 25 pound weight loss. [102]

As previously discussed, X-11 tablets in and of themselves will not cause any weight loss. A stringent diet, faithfully followed over a

prolonged period, will undoubtedly result in weight loss. However, the testimonials do not reflect the typical or ordinary experience of X-11 users, and their use without noting this fact is deceptive.

7. *Failure of advertisements to contain a health warning*

Brief comment is appropriate with respect to Paragraph Twelve of the complaint. The record establishes that phenylpropanolamine is a "vasoconstrictor" which tends to constrict the blood vessels and to raise blood pressure. It should not be ingested by persons with high blood pressure, heart disease, diabetes or thyroid disease except as directed by a physician. Failure to disclose this in respondents' advertising for X-11 tablets constitutes a failure to disclose a material fact. The "Caution" on the box of X-11 tablets warning that persons with these conditions should use X-11 tablets only as directed by a physician does not, in the view of the law judge, render it proper and nondeceptive for the advertisements to omit such a "Caution."

Members of the public who have high blood pressure, heart disease, diabetes or thyroid disease, and such persons are very numerous, have a right to the warning before making a trip to a store to buy respondents' X-11 tablets.

Respondents also market their X-11 tablets by mail order. Many of their advertisements contained a coupon for the prospective purchaser to fill out and mail to a retail store, or to Porter & Dietsch, to obtain a supply of tablets (for example, CX 18, 19 and 49, reprinted herein). Mail order purchasers, obviously, will not know about the "Caution" on the [103] box until they receive their X-11 tablets. The law is violated if the first contact with a prospective purchaser is deceptive. *Carter Products, Inc.* v. *Federal Trade Commission*, 186 F.2d 821, 824 (7th Cir. 1951); *Montgomery Ward & Co., Inc.* v. *Federal Trade Commission*, 379 F.2d 666 (7th Cir. 1967).

Nor does the fact that large numbers of the public do not know they have high blood pressure, heart disease, diabetes or thyroid disease render, as respondents urge, a warning in the advertisements "meaningless" (see Motion to Dismiss, p. 87). Significant numbers of the public with high blood pressure, heart disease, diabetes or thyroid disease do know of their condition, and a warning in X-11 advertisements would serve to dissuade them from using X-11 tablets without the guidance of a physician. It is significant that a disproportionate number of individuals with these conditions are overweight or obese and, absent such warning, a greater percent than that in the population at large would be attracted by respondents' advertisements. Additionally, a warning in the advertisements might well cause prospective purchasers of X-11 tablets who have the proscribed conditions, but who are ignorant of that fact, to check with a doctor before purchasing the tablets.

8. *Failure of advertisements to disclose that a highly restricted diet was integral to the X-11 "Plan"*

Paragraph Thirteen of the complaint alleges that respondents did not disclose in their advertising that a "highly restricted caloric diet was an integral part" of respondents' X-11 Reducing Plan. Examination of respondents' advertisements fully supports this allegation. Not only was there no disclosure that users of the X-11 tablets would have to follow a diet providing for a drastically reduced food intake to achieve significant weight losses, but the complete contrary [104] was represented. As has been described, and as the advertisements reprinted reveal, respondents affirmatively told the public that large poundages of body fat could be lost without "sticking to boring reducing diets," without "starvation dieting hunger," etc. Failure of respondents' X-11 advertisements to disclose that users were required to follow a low-calorie diet constituted a failure to disclose a material fact "likely to affect [the public's] consideration of whether or not to purchase said product."

9. *Collateral estoppel, stare decisis and res judicata*

As noted, respondents Porter & Dietsch, William H. Fraser, Kelly Ketting Furth and Joseph Furth filed amended answers pleading an affirmative defense that the "Commission is precluded from bringing this proceeding . . . under principles of collateral estoppel and/or stare decisis." Respondent Pay'n Save Corporation likewise filed an amended answer raising these affirmative defenses, and added "res judicata."

The basis for these defenses is the contention that the Commission and the Postal Service have already litigated the issue or issues in this proceeding, and have resolved them in favor of respondents. The cases respondents refer to are *Alleghany Pharmacal, supra*, and *Hanover House* and *Romar Sales, supra*, (see Appendix to Motion to Dismiss, p. 60).

The doctrines of res judicata and collateral estoppel are applicable to bar a second suit based on the same cause of action, or to bar relitigation of an issue or issues previously litigated. *Lawlor* v. *National Screen Service*, 349 U.S. 322, 326 (1955). The issues in *Alleghany Pharmacal, Hanover House* and *Romar* are not the same as the issues in this proceeding. [105]

The issue in this proceeding *inter alia* is whether X-11 tablets, containing phenylpropanolamine, will bring about the significant, large weight losses of virtually any amount held out to the public in respondents' advertising, not whether, for example, phenylpropanolamine has any significant pharmacological value as an appetite suppressant or weight-reducing agent. See *Alleghany Pharmacal*, 75 F.T.C. 996-97, *Hanover House* and *Romar Sales*. (Appendix in Support of Motion to Dismiss, pp. 6-7).

Where the issues are different, even if similar the Commission plainly cannot be estopped. *J. C. Martin Corp.* decision of the Commission of July 6, 1964, CCH Trade Reg. Rep., 1963-65 Transfer Binder, ¶16, 976, p. 22,054, *aff'd. J. C. Martin Corp.* v. *Federal Trade Commission*, 346 F.2d 147, 148 (3rd Cir. 1965), *Federal Trade Commission* v. *Raladam Co.*, 316 U.S. 149 (1942).

With respect to the defense of "stare decisis," that doctrine applies to principles of law, not to matters of fact. There were no principles of law enumerated in *Alleghany Pharmacal*, or in *Hanover House* and *Romar Sales*, binding on the Commission in this matter. Those proceedings do not preclude the Commission from litigating this matter.

10. *Responsibility of William H. Fraser*

As prior findings disclose, the responsibility of individual respondent William H. Fraser is clear, and it is essential that he be covered by the order in his individual capacity. *Standard Educators, Inc.*, 79 F.T.C. 858, 892-99 (1971), *aff'd. Standard Educators, Inc.* v. *Federal Trade Commission*, 475 F.2d 401 (D.C. Cir. 1973), *cert. denied*, 414 U.S. 828 (1973); *Coran Bros. Corp.*, 72 F.T.C. 1, 24-25 (1967); *Fred Meyer, Inc.* v. *Federal Trade Commission*, 359 F.2d 351, 367-68 (9th Cir. 1966), modified on another point, 390 U.S. 341 (1968). [106]

11. *Responsibility of Kelly Ketting Furth and Joseph Furth*

There is no warrant for relieving either Kelly Ketting Furth or Joseph Furth of responsibility for the deceptive advertising of X-11 tablets. Both were active participants in the preparation and dissemination of the advertisements, and knew or should have known of the deceptions involved. *Carter Products, Inc.* v. *Federal Trade Commission*, 323 F.2d 523, 533-34 (5th Cir. 1963); *Doherty, Clifford, Steers & Shenfield, Inc.* v. *Federal Trade Commission*, 392 F.2d 921, 928 (6th Cir. 1968); *ITT Continental Baking Co., Inc.*, CCH Trade Reg. Rep. ¶20,464, pages 20,383-85 (Order of October 19, 1973),

modified and aff'd *ITT Continental Baking Co.* v. *Federal Trade Commission*, 532 F.2d 207 (2nd Cir. 1976).

12. *Responsibility of Pay'n Save*

There is no dispute that Pay'n Save Corporation did not originate any of the claims or representations disseminated to the public in the advertisements for X-11 tablets. In the opinion of the law judge, however, this fact does not relieve Pay'n Save of responsibility. As the findings describe, Pay'n Save either received the mats or other materials from Porter & Dietsch and placed these advertisements in various media, or the advertising material was sent directly to the news media and held by them until Pay'n Save authorized publication. The fact is, however, that major newspaper advertisements were published over Pay'n Save's corporate name which made claims and representations to the public for X-11 tablets which were false, misleading and deceptive.

It would be unreasonable to permit Pay'n Save now to avoid responsibility for disseminating deceptive advertising on the ground that Porter & Dietsch furnished the advertisements. Such an outcome would [107] allow Pay'n Save to disseminate false advertising over its name with impunity, so long as it obtained the advertisements from a supplier. There is no foundation for such a position in reason or logic and, in the view of the undersigned it is contrary to the public interest.

Holding Pay'n Save responsible for false, misleading and deceptive representations disseminated over its own corporate name is not unfair, and does not place an unreasonable burden on Pay'n Save. In the case of supplier furnished advertisements Pay'n Save, or any other retail chain similarly situated, may simply elect not to publish the advertisements if it does not know whether or not the claims and representations contained in them are true. Nothing compelled Pay'n Save to publish the Porter & Dietsch advertisements here involved, and nothing in this ruling requires Pay'n Save to "maintain a staff of scientists and lawyers" to screen such advertisements. However, since Pay'n Save determined to publish advertisements furnished by Porter & Dietsch, and in effect to disseminate the claims and representations therein as its own, it must, in the view of the undersigned, as any other advertiser, assume responsibility for the claims and representations communicated to the public.

There is nothing extraordinary in imposing such a standard upon Pay'n Save. The rationale of *Pfizer, Inc., supra*, applies to any firm making claims and representations for products to the public. As the

Commission remarked over 15 years ago in the case of an advertising agency, the argument of Pay'n Save "is merely another variation of the oft-repeated effort to avoid responsibility for a violation of a statute by shifting it to another." *Colgate-Palmolive Co.*, 59 F.T.C. 1452, 1471 (1961), final order aff'd, *Federal Trade Commission* v. *Colgate-Palmolive Co.*, 380 U.S. 374 (1965). Nothing in this ruling prevents Pay'n Save from advertising suppliers' products for [108] resale. The ruling is only that, where Pay'n Save elects to publish advertisements making affirmative claims and representations for products, Pay'n Save assumes responsibility for the truthfulness of the claims and representations made.

MOTION TO DISMISS

The motion to dismiss filed by respondents (except Pay'n Save Corporation) on March 29, 1976, is hereby denied in accordance with what has been said in this initial decision.

IV

CONCLUSIONS

1. The Federal Trade Commission has jurisdiction over the corporate and individual respondents in this proceeding, and over their acts and practices in the advertising, promotion, marketing and sale of X-11 tablets.

2. The X-11 tablets, contained in packages marked "X-11 Reducing Plan," are "drugs" within the meaning and intent of Section 15(c) of the Federal Trade Commission Act.

3. Respondents have disseminated unfair, false, misleading and deceptive advertisements, statements and representations in the promotion, marketing and sale of X-11 tablets, and respondents' advertisements constitute "false advertisements" as that term is defined in the Federal Trade Commission Act.

4. The dissemination by respondents of unfair, false, misleading and deceptive advertisements, statements and representations in the promotion, marketing and sale of X-11 tablets has had, and now [109] has, the capacity and tendency to mislead members of the public into the erroneous and mistaken belief that such advertisements, statements and representations were, and are, true and free of material omissions, and into the purchase of substantial quantities of X-11 tablets by reason of such erroneous and mistaken belief.

5. The dissemination by respondents of unfair and false, misleading and deceptive advertisements, statements and representations in the promotion, marketing and sale of X-11 tablets, were, and are, to

the prejudice and injury of the public, and of respondents' competitors, and constituted, and now constitute, unfair and deceptive acts and practices in or affecting commerce, and unfair methods of competition in or affecting commerce, in violation of Sections 5 and 12 of the Federal Trade Commission Act.

6. This proceeding is in the public interest.

V

REMEDY

Brief comment respecting the order should be made. Broad product coverage with respect to respondents Porter & Dietsch and William H. Fraser is essential to ensure that violations similiar to those reflected in this record do not occur in the future. *Federal Trade Commission* v. *Ruberoid*, 343 U.S. 470, 473 (1952); *Federal Trade Commission* v. *National Lead*, 352 U.S. 419, 428-30 (1957). The authority of the Commission to issue an order extending to all products to prevent future violations is well established. *Consumer Sales Corp.* v. *Federal Trade Commission*, 198 F.2d 404 (2nd Cir. 1952); *Niresk Industries, Inc.* v. *Federal Trade Commission*, 278 F.2d 337, 342-343 (7th Cir. 1960), rehearing denied June 8, 1960, *cert. denied*, 364 U.S. 883. *Carter Products, Inc.* v. *Federal Trade Commission*, [110] 323 F.2d 523, 532-33 (5th Cir. 1963); *Western Radio Corp.* v. *Federal Trade Commission*, 339 F.2d 937, 940 (7th Cir. 1964), *cert. denied*, 381 U.S. 938; *Benrus Watch Company* v. *Federal Trade Commission*, 352 F.2d 313, 324 (8th Cir. 1965), *cert. denied*, 384 U.S. 939 (1966); *Firestone Tire & Rubber Company*, 481 F.2d 246 (6th Cir. 1973). Where required the order applicable to the foregoing respondents extends to "X-11 tablets or any other product." Where inappropriate the provisions have been narrowed.

As stated earlier, where human health is at stake, and other factors of a serious nature to the public are involved, *Pfizer, Inc.*, *supra*, 81 F.T.C. at 64, respondents must, in the opinion of the undersigned, have adequate, well-controlled scientific tests to support product claims and representations disseminated. Further, to prevent evasion of this standard, and to make certain that claims and representations disseminated requiring support by adequate, well-controlled scientific tests are in truth so supported, the order requires respondents, prior to disseminating such claims and representations, to have submitted such tests to the Commission for acceptance as fully substantiating the claims and representations being made.

Respondents, however, are not limited with respect to those who

may conduct such tests, inasmuch as it is the nature and validity of the tests which is important, not who conducts them.

A provision has also been inserted requiring disclosure of the details and circumstances associated with a result publicized in a testimonial. As shown herein, testimonials were disseminated by respondents in which women were quoted as having lost significant, large amounts of body weight, for example, 40 lbs., 80 lbs. For advertisements to be fully truthful, the [111] full facts and circumstances surrounding such weight losses should be disclosed. The public should be told whether such women adhered to drastic low-calorie diets while using respondents' X-11 tablets, or engaged in strenuous reducing exercises, how long it took to achieve the weight loss, and the like. Such are material facts relevant to product claims and representations for diet or reducing pills.

Further, in the view of the undersigned, respondents must be prevented from representing that body weight may be lost through the use of X-11 tablets, or any similar preparation, without disclosing the amount of such weight loss attributable to the X-11 tablets, or similar preparation, which is substantiated by adequate, well-controlled scientific tests. If tests substantiate only a weight loss of a fraction of a pound a week, attributable to X-11 tablets or similar preparation, for a few weeks before drug tolerance or other factors end such weekly loss, it would be misleading to hold out to the public a generalized claim without disclosing that it amounted to only a fraction of a pound per week, and was limited in duration.

Finally, the order prohibits respondents from attempting to mislead or misleading the public that a reducing "plan," "regimen," or "program" is being offered when in reality respondents are simply marketing pills or tablets.

VI

ORDER

It is ordered, That respondents Porter & Dietsch, Inc., a corporation, its successors and assigns, and its officers, and William H. Fraser, individually and as an officer of said corporation, and respondents' agents, representatives and employees, directly or through any corporation, subsidiary, division or other [112] device, in connection with the advertising, offering for sale, sale or distribution of X-11 tablets, or of any other preparation of similar composition or of similar properties, or dietary aid containing phenylpropanolamine, in or affecting commerce, as "commerce" is defined in the Federal Trade Commission Act, do forthwith cease

and desist from representing orally, in writing, or in any manner, directly or by implication, that users of X-11 tablets, or of any of the foregoing preparations, products or aids, can lose weight without restricting their accustomed caloric intake and while they continue to eat the foods of their choice (or words of similar import or meaning).

It is further ordered, That respondents Porter & Dietsch, Inc., a corporation, its successors and assigns, and its officers, and William H. Fraser, individually and as an officer of said corporation, and respondents' agents, representatives and employees, directly or through any corporation, subsidiary, division or other device, in connection with the advertising, offering for sale, sale or distribution of X-11 tablets, or any other product potentially affecting human health or safety, in or affecting commerce, as "commerce" is defined in the Federal Trade Commission Act, do forthwith cease and desist from representing orally, in writing, or in any manner, directly or by implication, that X-11 tablets, or any other product potentially affecting human health or safety, will be effective in producing any type of result, unless at the time such representation is made:

1. The representation is fully substantiated by adequate, well-controlled scientific tests accepted as such by the Federal Trade Commission,

2. the results, and methodology of such tests, together with with original data collected, [113] have been furnished to the Federal Trade Commission as documents available for public inspection,

3. copies of a brief but comprehensive written summary of the test results and methodology, in terms which are understandable to the average member of the public and which disclose the nearest place or places at which the complete test results, data and methodology may be inspected, are available to the public by mail upon request, and

4. any advertisement in which the representation is made shall clearly and conspicuously disclose that such summary may be obtained by mail upon request, and shall include the address to which such requests should be directed.

It is further ordered, That respondents Porter & Dietsch, Inc., a corporation, its successors and assigns, and its officers, and William H. Fraser, individually and as an officer of said corporation, and respondents' agents, representatives and employees, directly or through any corporation, subsidiary, division or other device, in connection with the advertising, offering for sale, sale or distribution of X-11 tablets, or any other product, in or affecting commerce, as

"commerce" is defined in the Federal Trade Commission Act, do forthwith cease and desist from: [114]

1. Using any testimonial for X-11 tablets or any other product which reports a result unless the testimonial or a related disclosure in close conjunction therewith reveals clearly and conspicuously the typical or ordinary experience of members of the public with such product.

2. Using any testimonial for X-11 tablets or any other product which reports a result unless the testimonial or a related disclosure in close conjunction therewith reveals clearly and conspicuously the full details and circumstances associated with the result.

3. Representing orally, in writing, or in any manner, directly or by implication, that X-11 tablets or any other product contain one or more unique ingredients or components, unless respondents can establish that said ingredient(s) or component(s) are unique to such product.

It is further ordered. That respondents Porter & Dietsch, Inc., a corporation, its successors and assigns, and its officers, and William H. Fraser, individually and as an officer of said corporation, and respondents' agents, representatives and employees, directly or through any corporation, subsidiary, division or other device in connection with the advertising, offering for sale, sale or distribution of X-11 tablets, or of any other preparation of similar composition or of similar properties, or dietary aid containing phenylpropanolamine, or any other dietary aid or purported weight-reducing product, in or affecting commerce, as "commerce" is defined in the Federal Trade Commission Act, do forthwith cease and desist from: [115]

1. Representing orally, in writing, or in any manner, directly or by implication, that users of X-11 tablets, or of any of the foregoing preparations, products or aids, will lose body weight without disclosing clearly and conspicuously the amount of such weight loss, on a per-week basis, attributable to X-11 tablets, or to any of the foregoing preparations, products, or aids, which is supported by adequate, well-controlled scientific tests.

2. Attempting to mislead or misleading the public that a "plan," "regimen" or "program" is being offered when in truth respondents are simply marketing X-11 tablets, or one of the foregoing preparations, products or aids.

It is further ordered, That respondents Porter & Dietsch, Inc., a corporation, it successors and assigns, and its officers, and William H. Fraser, individually and as an officer of said corporation and respondents' agents, representatives, and employees, directly or through any corporation, subsidiary, division or other device, do

forthwith cease and desist from disseminating or causing to be disseminated by United States mail or by any means in or having an effect upon commerce, as "commerce" is defined in the Federal Trade Commission Act, any advertisement for X-11 tablets, or for any preparation of similar properties, or for any dietary aid containing phenylpropanolamine, unless respondents clearly and conspicuously disclose the following statements, as applicable, with nothing to the contrary or in mitigation thereof:

This product requires users to "diet," that is, to restrict their caloric intake. Users cannot lose weight without restricting their accustomed caloric intake. [116]

It has not been established that this product is effective in promoting any significant or lasting weight loss.

WARNING: This product can cause a temporary increase in blood pressure. Persons with high blood pressure, heart disease, diabetes or thyroid disease should use this product only as directed by a physician. Overweight individuals are more likely to have such conditions than other persons, and often do not know it. See your doctor before taking this product.

It is further ordered, That respondents Pay'n Save Corporation and Kelly Ketting Furth, Inc., corporations, their successors and assigns, and their officers, and Joseph Furth, individually and as an officer of Kelly Ketting Furth, Inc., and respondents' agents, representatives and employees, directly or through any corporation, subsidiary, division or other device, in connection with the advertising, offering for sale, sale or distribution of X-11 tablets, or any other diet aid or purported weight-reducing food, drug or device, as "food," "drug," and "device" are defined in the Federal Trade Commission Act, do forthwith cease and desist from disseminating or causing to be disseminated by United States mail or by any means in or having an effect upon commerce, as "commerce" is defined in the Federal Trade Commission Act, any advertisement which contains a representation or testimonial for such product prohibited by this order, or which omits a disclosure for such product required by this order. [117]

It is further ordered, That all respondents forthwith deliver a copy of this order to each operating division and subsidiary, to all present and future personnel of respondents engaged in the preparation, creation or placing of advertising of foods, drugs or devices on behalf of respondents, and to all present and future agencies engaged in the preparation, creation or placing of such advertising for respondents,

and that respondents secure from each such person and agency a signed statement acknowledging receipt of said order.

It is further ordered, That respondents immediately recall and retrieve, from all persons and entities that have engaged in the advertising or promotion of X-11 tablets within the past two years, all advertising mats and promotional material which contain a representation or testimonial prohibited by this order or which omit a disclosure required by this order. Respondents Porter & Dietsch, Inc., and William H. Fraser shall also deliver written notice of the requirements of this order to all distributors and retailers of products marketed by said respondents, and shall institute a program of continuing surveillance adequate to reveal whether they are complying with said requirements including the above recall provision. In the event that nonconformity with any such requirements is discovered, said respondents shall immediately cease supplying all products to said distributors or retailers until adequate, reliable assurance of conformity is obtained.

It is further ordered, That all respondents shall maintain complete business records relative to the manner and form of their compliance with this order. Respondents shall retain each such record for at least three years, and shall retain substantiation and other documentation at least two years beyond the last dissemination of any representation or testimonial contingent thereon under the provisions of this order. [118] Upon reasonable notice, respondents shall make any and all such records available for inspection and photocopying by authorized representatives of the Federal Trade Commission at respondents' place of business or other properly designated location. For respondents Porter & Dietsch, Inc., and William H. Fraser, such records shall include (but not be limited to) all advertising, sales memoranda, policy directives, the basis for all applicable advertising claims, correspondence with persons who place advertising, and other pertinent documents.

It is further ordered, That all respondents herein notify the Commission at least thirty (30) days prior to any proposed change in a corporate respondent, such as dissolution, assignment or sale resulting in the emergence of any successor corporation or corporations, the creation or dissolution of subsidiaries, or any other change in said corporations which may affect compliance obligations arising out of this order.

It is further ordered, That each individual respondent named herein for a period of five (5) years from the effective date of this order promptly notify the Commission of the discontinuance of his present business or employment and/or of his affiliation with a new

business or employment. If applicable each such notice shall include the respondent's new business address and a statement of the nature of the business or employment in which he is newly engaged as well as a description of his duties and responsibilities in connection with the business or employment. The expiration of the notice provision of this paragraph shall not affect any other obligation arising under this order. [119]

It is further ordered, That the respondents herein shall, within sixty (60) days after service of this order, file with the Commission a written report setting forth in detail the manner and form of their compliance with this order.

Opinion of the Commission

By Collier, *Commissioner:*

This proceeding challenges the lawfulness of advertising claims made for "X-11" tablets, a non-prescription drug sold as a weight reduction product.[1] In their appeal from the [2] Administrative Law Judge's ("ALJ's") proposed findings, conclusions, and recommended order, respondents[2] make numerous assertions of error on a broad range of factual [3] and legal issues. Contesting the initial decision page by page, respondents object to the ALJ's treatment of the meaning of the advertisements, the falsity of the claims, procedural

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[1] The complaint invoked Sections 5 and 12 of the Federal Trade Commission Act. In pertinent part, Section 5 prohibits "unfair or deceptive acts or practices" and Section 12 prohibits the dissemination of "false advertisements" of food, drug, (medical) device and cosmetic products. "False advertisements" are those that are "misleading in a material respect," in light of (among other things)

> not only representations made or suggested by statement, word, design, device, sound, or any combination thereof, but also the extent to which the advertisement fails to reveal facts material in light of such representations, or material with respect to consequences which may result from the use of the commodity to which the advertisement relates under the conditions prescribed in such advertisement or under such conditions as are customary and usual. [§15, 15 U.S.C. 55 (1914)]

[2] The respondents in this proceeding are Porter & Dietsch, Inc., which packages X-11 tablets and sells them through the mail and through retail drug stores (I.D. 1); Kelly Ketting Furth, Inc., an advertising agency, which works with Porter & Dietsch to prepare advertising for X-11 tablets (I.D. 4, 143-145); Pay'n Save Corporation, a chain of retail drug and sundry stores which sells X-11 tablets and disseminates X-11 advertising which has been prepared by Porter & Dietsch and Kelly Ketting Furth (I.D. 7, 149(b)-154); William H. Fraser, president and sole stockholder of Porter & Dietsch (I.D. 2, 141-142); and Joseph Furth, a vice-president of Kelly Ketting Furth, Inc., and an account executive for that concern in charge of Porter & Dietsch X-11 advertising (I.D. 5, 143-149(a)). The following abbreviations are used in this opinion:

I.D. — Initial Decision, Finding No.
I.D. p. — Initial Decision, Page No.
CX — Complaint Counsel's Exhibit No.
RX — Respondent's Exhibit No.
Tr. — Transcript of Testimony, Page No.
RB — Respondents' Appeal Brief to the Commission, Page No.
RRB — Respondents' Reply Brief to the Commission, Page No.

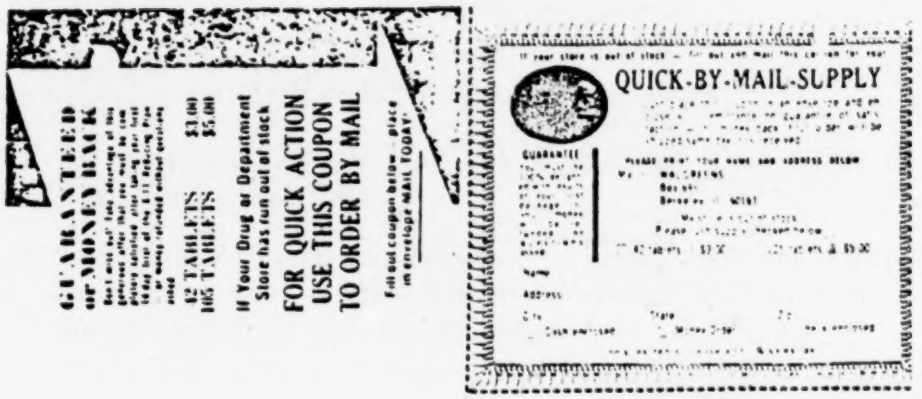
Respondent Pay'n Save has filed its own briefs in this appeal, while "adopting" the arguments of the other respondents as to the truth or falsity of the advertising in question. References to Pay'n Save's separate briefs will either be apparent in context or more specifically identified.

rulings, allegedly erroneous legal rulings, and the separate liability of certain respondents.

Meaning of the Advertisements

The complaint alleges, and the ALJ found, that respondents' advertisements represent:

- that users of X-11 tablets can lose weight without restricting their accustomed caloric intake and while they continue to eat the foods of their choice (Complaint, ¶ 9; I.D. 39);
- that respondents have a reasonable basis from which to conclude that substantially all users of X-11 tablets will lose a significant amount of weight (Complaint, ¶ 9; I.D. 47); and
- that the X-11 tablet contains a unique ingredient (Complaint, ¶ 9; I.D. 48).



[5] Although respondents do not contest that the advertisements are theirs, they deny that the ads conveyed any of these alleged claims.

We approach the task of reviewing the ALJ's findings on the meaning of the ads with utmost care. In particular, we are acutely aware that there is a strong public interest in avoiding constraints on truthful advertising. *See Bates* v. *Arizona*, 97 S. Ct. 2691 (1977); *Virginia State Board of Pharmacy* v. *Virginia Citizens Consumer Council, Inc.*, 425 U.S. 748 (1976); and *Bigelow* v. *Virginia*, 421 U.S. 809 (1975). In *Virginia State Board* the Supreme Court observed:

> [the] consumer's interest in the free flow of information of commercial information . . . may be as keen, if not keener by far, than his interest in the day's most urgent political debate . . . So long as we preserve a predominantly free enterprise economy, the allocation of our resources in large measure will be made through numerous private economic decisions. It is a matter of public interest that those decisions, in the aggregate, be intelligent and well-informed. To this end, the free flow of commercial information is indispensable. 425 U.S. at 763-65.

The public interest in the free flow of truthful information makes the task of interpreting advertisements a delicate one. However, commercial speech is not entitled to the same unfettered constitutional protection afforded political speech. Deceptive commercial speech has no constitutional protection. *See Virginia State Board*, 425 U.S. n. 24 at 773-74 and *Bates*, 97 S. Ct. at 2708-09. Deceptive commercial speech does not aid consumers in making their purchasing decisions and may cause economic injury to those consumers who purchase the advertised product because of the deception. It also reduces the effectiveness of all advertising by casting doubt on its reliability. Therefore, although sensitive to the public interest in the free flow of commercial speech, we serve the same public goals when we meet our statutory obligations by prohibiting deceptive advertising. [6]

The ALJ applied common sense and expertise in setting forth the overall effects and net impressions that the advertisements conveyed,[3] and he supported his interpretations with references to the words used, the pictorial displays, and the layouts employed.

Respondents complain that use of these well-accepted techniques

[3] Such an approach is not merely permissible, but is required in order to assess whether advertising is "false" under Section 15 of the FTC Act, *supra* n. 1 at 1, and the Commission has long been upheld in reading advertising for its total or general impression on the consuming public. *See FTC* v. *Colgate-Palmolive Co.*, 380 U.S. 374, 385 (1965) ("the finding of a Section 5 violation in this field rests . . . heavily on inference and pragmatic judgment"); *Murray Space Shoe Corp.* v. *FTC*, 304 F.2d 270, 272 (2d Cir. 1962); *Charles of the Ritz Distribs. Corp.* v. *FTC*, 143 F.2d 676 (2d Cir. 1944); *Exposition Press, Inc.*, v. *FTC*, 295 F.2d 869, 872 (2d Cir. 1961), *cert. denied*, 370 U.S. 917 (1962).

for discerning the meaning of advertisements distorted them and wrenched various words and phrases from their context.[4] We have carefully reviewed each of these alleged examples of gerrymandering of the advertisements and we find that respondents' arguments are without merit. [7]

The Advertising and Sale of X-11 Tablets The ALJ found that respondents marketed "X-11 tablets"; respondents argue that they marketed the "X-11 Reducing Plan." The difference is significant, we are told, because the "plan" consisted of ingestion of the tablets plus adherence to a restricted diet. Respondents virtually concede that consumption of X-11 tablets alone, without dieting, will not produce any of the weight reduction results that the advertisements proclaim (RB 31; I.D. 53).[5] The tablets contain phenylpropanolamine hydrochloride ("PPA"); and respondents argue that PPA is an appetite suppressant that helps people stay on restricted diets. They contend, in short, that the tablets are part of the plan and not the plan itself.

Respondents emphasize the number of times that the word "plan" is used in the advertisements ,and the care with which the advertisements were designed to assure that express claims of weight loss were credited to the "plan." The ALJ considered that argument but chose instead to ascertain the net impression conveyed by the advertisements. His choice of approach was correct and we affirm his findings. [8]

Although the word "plan" was often used in the advertisements, it was not described as a rigorous program of reduced caloric intake. On the contrary, express claims for the plan stressed its capacity to allow consumers to "eat well," to avoid "starvation dieting hunger" and "boring reducing diets," and to have "3 sensible meals a day plus 'tween meal snacks."[6] These claims were coupled with and overshadowed by ubiquitous references to X-11 tablets which were described as the key to attaining these objectives.

Respondents also object to the ALJ's reference to consumer testimonials in Findings 19 and 20. These letters show that some consumers, even satisfied ones, perceived that respondents were selling tablets or pills rather than a plan. We reject the argument

[4] Respondents' zeal in pursuing this line of attack exceeds reasonable bounds when on several occasions they argue that the ALJ's findings display bias and prejudice (RB 35, 37, 55, 57).

[5] In addition, respondents' package insert candidly admonishes that "weight loss is only accomplished when a minimum of calories are consumed" (I.D. 52), and individual respondent Joseph Furth, the advertising account executive for Porter & Dietach, cautioned the company to avoid emphasizing "tablets" in the advertising because "the pills will not reduce weight an iota. . . . [i]t is the 'Plan' that will keep us out of hot water" (CX 164).

[6] The diet which respondents assert was part of the "plan" was set forth in the package insert. In stark contrast to the advertising claims, the insert detailed an extremely strict program of dieting which the ALJ correctly found did not permit between meal snacks and did constitute a starvation or near starvation diet.

that this evidence is not probative and the further argument that customers' perceptions are not relevant to the allegation that respondents sold X-11 tablets. At the very least, the letters show that respondents' advertisements did not so indelibly implant [9] the "X-11 plan" in consumers' minds that they refrained from referring to the product as "tablets" or "pills."[7]

In a related sally, respondents attack a phrase in one of the several relevant findings (I.D. 12) that is not to be found in the advertising itself (RB 36). But the ALJ never found to the contrary and he made it clear that the words were his and not the advertiser's by the customary technique of placing quotation marks around some words and not others. Respondents create and then flog a strawman. The advertisement itself was made a part of the partially disputed finding and we conclude that the ALJ's interpretation of it was correct.

Claims of Weight Losses Without Dieting Based on a thorough review of the challenged advertisements, the ALJ found that respondents' advertising conveyed the impression that "users of X-11 tablets could lose body weight without dieting or consciously or materially changing their eating habits, . . . 'without restricting their accustomed caloric intake and while they continue to eat the foods of their choice.' " (I.D. 39) Respondents complain that this and other relevant findings (I.D. 28–38) rest on the erroneous repetition of selective excerpts from the advertisements. In adopting the contested findings, we note that the phrases which the ALJ highlighted were prominently featured in the advertising and formed the themes which the advertisements themselves constantly repeated. [10]

The ALJ's findings on this question are entirely consistent in our view with Commission experience in dealing with advertising claims for weight reduction products[8] [11] and with common sense. It is

[7] Another objection to the testimonial letters is based on a stipulation among the parties that consumer witnesses would not be called during the proceeding. Even if, by some stretch of the imagination, the stipulation were construed to cover documentary materials, respondents waived any objections on these grounds, first, by introducing similar letters of their own and, second, by failing to object to the introduction of complaint counsel's exhibits into evidence.

[8] *See, e.g., McGowan Laboratories, Inc.*, 11 F.T.C. 125 (1927); *Dispensary Supply Co.*, 20 F.T.C. 346 (1935); *Dispensary Supply Co.*, 22 F.T.C. 735 (1936); *Raladam Co.*, 24 F.T.C. 475 (1937), *aff'd* 316 U.S. 149 (1942); *Germania Tea Co.*, 25 F.T.C. 150 (1937); *Glenn Laboratories, Inc.*, 25 F.T.C. 302 (1937); *Wolf Drug Co.*, 25 F.T.C. 306 (1937); *Korjena Medicine Co.*, 26 F.T.C. 1013 (1938); *Helena Rubinstein, Inc.*, 27 F.T.C. 1 (1938); *Reliable Specialty Corp.*, 27 F.T.C. 627 (1938); *Gates Medicine Co., Inc.*, 27 F.T.C. 1040 (1938); *Isabella Laboratories*, 28 F.T.C. 38 (1939); *Alberts*, 29 F.T.C. 210 (1939), *aff'd as modified*, 118 F.2d 669 (9th Cir. 1941); *American Clinical Laboratories, Inc.*, 29 F.T.C. 1389 (1939); *Jean Ferrell, Inc.*, 30 F.T.C. 647 (1940); *Le Flor Co.*, 30 F.T.C. 1086 (1940); *Chapman Health Products Co.*, 30 F.T.C. 1199 (1940); *Sekor Corp.*, 31 F.T.C. 895 (1940); *Progressive Medical Co.*, 31 F.T.C. 1111 (1940); *Thyrole Products Co.*, 31 F.T.C. 1399 (1940); *American Medicinal Products, Inc.*, 32 F.T.C. 1376 (1941), *aff'd*, 136 F.2d 426 (9th Cir. 1943); *Miller Drug Co.*, 32 F.T.C. 122 (1940); *Burtley Co.*, 33 F.T.C. 455 (1941); *Clara Stanton, Druggist to Women*, 34 F.T.C. 153 (1941), *aff'd*, 131 F.2d 105 (10th Cir. 1942); *Bentley Co., Mail Order Division*, 34 F.T.C. 110 (1941); *Battle Creek Drugs, Inc.*, 34 F.T.C. 651 (1942); *Montgomery Ward & Co.*, 34 F.T.C. 1471 (1942); *Gene Hughes Drug*

(Continued)

obvious that dieting is the conventional method of losing weight. But it is equally obvious that many people who need or want to lose weight regard dieting as bitter medicine. To these corpulent consumers the promises of weight loss without dieting are the Siren's call, and advertising that heralds unrestrained consumption while muting the inevitable need for temperance if not abstinence simply does not pass muster. Where dieting is required, there is simply no substitute for clear and conspicuous disclosure that dieting is required.

Claims that Respondents Possessed Substantiation for Claims of Significant Weight Losses by Substantially All Users Respondents concede the "partial correctness"[9] of the ALJ's finding that the advertising represents that "substantially all users of X-11 tablets would lose a significant, in fact, as large an amount of weight as they desired" (I.D. 47; RB 39). They object, however, to that portion of Finding 47 which construes the advertising as containing affirmative representations that they possessed a reasonable basis for the "significant-weight-losses-by-substantially-all-users" claim (RB 39). Respondents complain that the ALJ "cites no language" in Finding 47 representing that they had a reasonable basis for such a claim. The ALJ properly drew his conclusion from the evidence reviewed in I.D. 40–46, on which Finding 47 rests.

As the ALJ found, (I.D. 40–47) the extravagance of the weight-loss claims implies that substantiation exists, and respondents have included statements in their advertising such as: "Laboratory Science has perfected a tiny pre-meal tablet . . ." (I.D. 44) (CX 1, 2, 11, 35, 46–48, 50, 52, 56, 58, 61–62 ["X-11 is the PROVEN and SOUND method . . ."], 74, 79); "clinic tested ingredients" (CX 47, 49, 74); and "The X-11 Reducing Plan is medically recognized as an effective plan to lose ugly fat." (CX 74)[10] *See also* I.D. 123. These statements not only implied the existence of substantiation but they also represented that this substantiation consisted of competent scientific proof. [12]

Stores, Inc., 35 F.T.C. 20 (1942); *Peggie Moran Co.*, 35 F.T.C. 27 (1942); *E. Griffiths Hughes, Inc.*, 40 F.T.C. 448 (1945); *Zo-Lon Co.*, 41 F.T.C. 38 (1945); *Langendorf United Bakeries, Inc.*, 43 F.T.C. 132 (1946); *Mid-West Drug Co., Inc.*, 43 F.T.C. 349 (1947); *Natural Foods Institute*, 50 F.T.C. 434 (1953); *Marlene's, Inc.*, 50 F.T.C. 460 (1953), *aff'd*, 216 F.2d 556 (7th Cir. 1954); *Renor Co., Inc.*, 53 F.T.C. 1222 (1957); *Rennel Products*, 54 F.T.C. 719 (1957); *Rennel Sales*, 54 F.T.C. 725 (1957); *Bakers Franchise Corp.*, 59 F.T.C. 70 (1961), *aff'd*, 302 F.2d 258 (3d Cir. 1962); *Damar Products, Inc.*, 59 F.T.C. 1263 (1961), *aff'd*, 309 F.2d 323 (3d Cir. 1962); *Consumer Laboratories, Inc.*, 61 F.T.C. 910 (1962); *National Bakers Services, Inc.*, 62 F.T.C. 1115 (1963), *aff'd*, 329 F.2d 365 (7th Cir. 1964); *Stauffer Laboratories, Inc.*, 64 F.T.C. 629 (1964), *aff'd* 343 F.2d 75 (9th Cir. 1965); *Farrar, Straus and Co., Inc.*, 65 F.T.C. 253 (1964); and *Simeon Management Corp.*, 87 F.T.C. 1184 (1976), *appeal pending*, No. 76-2543 (9th Cir.). We omit consent agreements and stipulations. Falsely advertised weight reduction products have run the gamut from food and drugs to devices and cosmetics.

[9] Respondents repeat their argument that they advertised the virtues of the "X-11 Reducing Plan" rather than "X-11 Tablets." See pages 7–8 above.

[10] We amend I.D. 44 to include the latter statements. *See* Appendix.

Moreover, it is now well-established that in the absence of a contrary disclosure, a product claim necessarily carries with it a representation that "the party making it possesses a reasonable basis for so doing, and that the assertion does not constitute mere surmise or wishful thinking on the advertiser's part." *National Commission on Egg Nutrition*, 88 F.T.C. 89, 191 (1976), *modified*—— F.2d——(7th Cir. November 29, 1977). *See National Dynamics Corp.*, 82 F.T.C. 488 (1973), *modified*, 492 F.2d 1333 (2d Cir.) *cert. denied*, 419 U.S. 993 (1974); *Pfizer, Inc.*, 81 F.T.C. 23, 64 (1972).[11]

Respondents further argue that, by offering a "money back guarantee" (*e.g.*, CX 1), they qualified their claims and conveyed the message that X-11 would not cause substantially all users to lose a significant amount of weight. In our view, this argument stands common sense on its head. If anything, a money back quarantee reinforces in consumers' minds the sincerity of the advertisers' assertions, including those that are false and exaggerated.[12]

[13] *Unique Ingredient Claims* According to respondents, the ALJ "correctly found that which respondents admit - they advertised that their product contained a unique ingredient and that they intended phenylpropanolomine" [sic] (RB 40).[13]

The Falsity of the Claims

Because respondents have vigorously disputed the meaning that the ALJ ascribed to their advertisements, it is sometimes difficult to discern whether they also object to the findings that these claims were false.[14]

Claims of Weight Losses without Dieting Thus, the ALJ found, and we agree, that "[t]he representations of respondents in their

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[11] In *Pfizer* we suggested that the failure to possess a reasonable basis is unfair within the meaning of Section 5. The complaint here alleged that the product claims were deceptive. Whether an advertisement is analyzed from the standpoint of deception or unfairness the result is the same and so is the standard for evaluating the substantiating material. *National Dynamics Corp., supra*, 82 F.T.C. at 550 n. 10.

[12] *See* I.D. 46; FTC Guides Against Deceptive Advertising of Guarantees, 16 C.F.R. 239.7; *All State Industries of North Carolina, Inc.*, 75 F.T.C. 465, 488–489 (1969), *aff'd*, 423 F.2d 423 (4th Cir.), *cert. denied*, 400 U.S. 828 (1970). In our view, *Jeffries* v. *Olesen*, 121 F. Supp. 463 (S.D. Calif. 1954); *Pinkus* v. *Walker*, 61 F. Supp. 610 (D. N.J. 1945) (injunction granted), 71 F. Supp. 993 (D. N.J. 1947) (final order, *sub nom. Pinkus* v. *Reilly*), *aff'd*, 170 F.2d 786 (3d Cir. 1948), *aff'd, sub nom. Reilly* v. *Pinkus*, 338 U.S. 269 (1949); and *Jarvis* v. *Shackelton Inhaler Co.*, 136 F.2d 116, 121 (6th Cir. 1943), are not to the contrary. These cases involved a statute unlike the FTC Act requiring proof of "actual intent to deceive" or "actual fraud in fact" and it was found that the money-back guarantee negated that intent. *See Pinkus* v. *Walker*, 61 F. Supp. at 613–14, and *Jeffries* v. *Olesen*, 121 F. Supp. at 473.

[13] We have some difficulty, however, fathoming the remainder of respondents' argument. They object to the ALJ's finding that the advertisements represented that X-11 *tablets* were unique. We are at a loss to discover how respondents' product could contain a unique ingredient (PPA) without X-11 tablets (which were admittedly the product containing PPA) being unique to the very same extent. It also escapes us how consumers could draw any other inference.

[14] For example, to support their argument that the ads are literally truthful, respondents assert that they recommended a "balanced diet." They go on to assert that one who has a balanced diet "eats well" (RB 39). The syllogism is interesting but misses the point. Respondents' advertising conveys more than the restricted meaning to which respondents must cling in their defense.

advertisements that users of X-11 tablets could lose weight without restricting their accustomed caloric intake, and while continuing to eat foods of their choice, were false, misleading and deceptive." (I.D. 54. *See* I.D. 50-53.) Respondents seem to concede as much when they argue that "it is impossible for the user of an appetite suppressant . . . to consume the foods of their [14] choice. . . ." (RB 40)[15] Neither do they deny that the advertising represents that consumers using X-11 can lose weight while continuing to eat foods of their choice; instead, they contend that the "choices" represented "can fairly be construed to relate to" the restricted diet which is inserted into each X-11 box (RB 31). In fact, as the ALJ found, weight losses require a highly restrictive "starvation or near-starvation" diet and total abstinence from such foods as gravies, nuts, candy, mayonnaise, pastries, whole milk, fried foods, rich dressings, and rich desserts.[16] These are often the very foods that overweight consumers hope least to abandon along with their unwanted inches.

Unique Ingredient Claims Respondents raise no objections to Findings 123 or 124, which conclude that the advertisements falsely claim that X-11 tablets contain a unique ingredient (RB 53).

Claims of Substantiation for the Significant Weight-Loss-by-Substantially-All-Users Claim The major controversy surrounding the alleged falsity of the advertisements centers on the charge that respondents implicitly promised, but did not possess a reasonable basis for the claim that substantially all users of X-11 tablets can lose significant amounts of weight. The primary question thereby put in issue by the complaint is not whether the claims of weight loss are false but instead whether, at the time they were made, respondents possessed reasonable substantiation for them. [15]

In the course of the hearing, the scope of this inquiry was expanded. Rather than scrutinizing only the material that respondents possessed and relied upon in making their claims (including the claims that they had such material), the parties produced numerous experts and documents bearing upon the pharmacological properties of PPA. The initial decision sifts this evidence in painstaking detail, and we affirm the numerous findings of the ALJ on these matters. At the same time, this evidence is of limited utility to the extent that it strays from the narrower issue of the type and

[15] The full text of respondents' argument is, "In Findings 50-54 the Law Judge does not address the issue of why it is impossible for the user of an appetite suppressant such as phenylpropanolomine, to consume the foods of their choice, while consuming less, thus losing weight consistent with the findings in *Carlay*, *supra* and *Alleghany*, *supra*; and the testimony of complaint counsel's witnesses, Drs. Margan and Drenick, Tr. 308, 452."

[16] In lieu of these foods, respondents' "eat-well," open "choice" diet consisted of such breakfasts as a half grapefruit and black coffee or a glass of orange juice and black coffee; such lunches as tuna chunks, celery and carrot sticks, and a slice of bread or string beans, beets and spinach and a slice of bread; or such dinners as broiled chicken, tossed salad and a fresh fruit cup, or baked fish, raw cabbage salad and a cup of soup (CX 40).

quality of the substantiation material possessed and relied upon by respondents at the time they made their claims.

The ALJ concluded that only "adequate and well-controlled scientific studies or tests" would provide adequate substantiation for claims made for a drug product like X-11, sold for the treatment of overweight and obesity, because these conditions pose dangers to health (I.D. p. 99). We see no need to reach the question whether consumers expect this type and quality of substantiation simply because the advertised product is a drug. In the context of this advertising, consumers were led to understand that respondents had competent scientific tests to substantiate their claims.

During the investigation of this matter and during the hearing, respondents conceded that they had no tests, studies, scientific reports or other similar information to support their implied claim that they had a reasonable basis for their weight-loss representations (I.D. 56-60).

Instead, respondents contend that they relied on a recommended decision of a Commission hearing examiner (which was never adopted as a final agency decision), *Alleghany Pharmacal Corp., et al.*, 75 F.T.C. 990 (1969), the decision in *Carlay Co.* v. *FTC*, 153 F.2d 493 (7th Cir. 1946), some materials on the general properties of methylcellulose,[17] [16] and copies of two 1957 letters from the Food and Drug Administration to other companies (RB 21, 41).[18] These materials, according to the record, were not reviewed by Porter & Dietsch, William H. Fraser, or Pay'n Save, although Joseph Furth was shown the *Alleghany* and *Carlay* decisions, but were in the possession of Mr. Frank Gettleman, an attorney for Porter & Dietsch. Mr. Gettleman supplied these materials during the investigation of this matter to the Commission's staff in response to their request for substantiation for X-11 advertising claims (I.D. 56-62).

In addition, respondents refer us to a decision of the United States Postal Service which was rendered after issuance of the complaint in this proceeding,[19] materials mentioned in *Alleghany*, and testimony and documents on the efficacy or degree of use of PPA introduced into evidence in this proceeding, including reports of studies concerning PPA which were also published after the complaint

[17] Respondents do not appeal the ALJ's finding that respondents had no reasonable substantiation as to the methylcellulose contained in X-11 and that methylcellulose itself does not suppress the appetite (I.D. 122).

[18] Respondents object that the ALJ overlooked the FDA letters and the methylcellulose materials. Accordingly, we add an appropriate finding in the Appendix.

[19] In re Hanover House, P.S. Dkt. No. 2/143, and Romar Sales Corp., P.S. Dkt. No. 2/149 (Dec. 5, 1975) (consolidated; not reported). The Postal Service decision found, at most, that expert opinion was divided on the efficacy of PPA and that the complainant had not carried its burden of proving that PPA is ineffective. Like the hearing examiner's recommended decision in the *Alleghany* case, there was no finding that "substantially all users [of PPA] will lose a significant amount of weight."

issued. As we have indicated, such evidence is irrelevant to the question whether the respondents have, as alleged in the complaint, misrepresented that they had substantiation for their advertising claims at the time that the claims were made. In any event, none of these materials supports the claim that "substantially all users of X-11 tablets will lose a significant amount of weight." [17]

Carlay involved a different product altogether, a candy which, when ingested before meals, presumably spoiled the consumer's appetite. The Commission found that the advertising was deceptive but the court held that the Commission's conclusion was not supported by substantial evidence.[20] Recognizing the factual dissimilarity between the candy in *Carlay* and their own X-11 tablets, respondents argue that the *Carlay* case gives them a license to make unlimited efficacy claims ("substantial weight losses") for any product that is an "effective" appetite suppressant sold in conjunction with a restrictive diet "plan" (revealed in full only in a package insert) (RB 42). Later cases render this alleged defense untenable. See *Stauffer Laboratories, Inc.* v. *FTC*, 343 F.2d 75 (9th Cir. 1965); *Damar Prods., Inc.* v. *FTC*, 309 F.2d 323 (3d Cir. 1962). Moreover, *Carlay* did not address the question whether substantial amounts of weight could be lost by eating candy before each meal. Even if PPA were an "effective" appetite suppressant in the dosages provided in X-11, it would not follow that "substantially all users of X-11 tablets will lose a significant amount of weight."

Alleghany involved a challenge to advertising claims for "Hungrex," a weight reduction product which also contained PPA. Respondents argue that the *Alleghany* case, or at least some of the evidence recited in the hearing examiner's recommended decision in that case, provides substantiation for the proposition that "substantially all users of X-11 tablets will lose a significant amount of weight." [18]

The hearing examiner in *Alleghany* concluded that the allegations of the Commission's revised complaint on reopening had not been established by a preponderance of the evidence, 75 F.T.C. at 1034. "[W]ithout expressing any opinion as to the accuracy of the findings and conclusions in the [hearing examiner's] Certification of Record," the Commission concluded that "it would not be in the public interest to pursue this matter further" and dismissed the complaint without prejudice, while leaving an earlier consent order against

[20] We reject the implication of respondents' argument that years after a court decision finding a failure of the government to establish the falsity of advertising claims, an advertiser can rely on the decision notwithstanding the present state of medical or scientific knowledge. We do not understand that to be the law, *see FTC* v. *Raladam Co.*, 316 U.S. 149, 150-151 (1942); *Hastings Mfg. Co.* v. *FTC*, 153 F.2d 253, 254, 258 (6th Cir. 1946), nor would we consider it to be defensible public policy.

Alleghany Pharmacal in effect, *Id.* at 1036. Moreover, the hearing examiner's unadopted, recommended decision in *Alleghany* found, at most, that PPA is an "effective appetite depressant in the treatment of obesity," *Id.* at 1033.[21] This conclusion falls far short of a finding of significant weight losses by substantially all users.

Respondents also contend that they relied on evidence discussed in the *Alleghany* decision (RB 21). However, respondents did not possess anything more than the discussion of these materials contained in *Alleghany* itself and, as the ALJ found (I.D. 61), the discussion, putting aside the inconclusive disposition of the case, does not support X-11 advertising claims.

The first example cited is a test done by Dr. Edward Settel, who testified in *Alleghany* that he had done a study of 30 persons who were 10 percent or more overweight. The entire group was on a 900 calorie a day diet. No further details of the study are provided. Dr. Settel concluded that PPA is a "more effective anorexiant agent" than a placebo. He did not testify as to the extent of weight [19] loss, if any, of the persons tested. 75 F.T.C. at 1016-1017. Dr. Frederick B. Bohensky testified that he had treated several thousand patients for obesity in his practice in Brooklyn, was familiar with PPA, used it in his practice, had tested it on dogs, and concluded that it was an "effective anorexigenic and weight reducing agency" in dosages of 75 mg. per day. *Id.* at 1019-1020. Dr. Theodore Feinblatt testified that, on the basis of a study he had done, a 75 mg. dose of PPA "effective as an anorexiant agent for the treatment of obesity." No details of the study are mentioned *Id.* at 1023. Dr. Raymond W. Healy, a general practitioner primarily interested in obesity, had been giving his patients amphetamine to reduce their appetites while they were on low calorie diets. He gave 30 patients PPA instead, and concluded that PPA was "effective in reducing the appetite in about 80 percent of his patients involved in the test." *Id.* at 1022. Dr. Harold Silverman criticized a study relied upon in an FDA proceeding against a similar product,[22] which was done by Dr. Joseph F. Fazekas. *Id.* at 1027. Dr. Fazekas had concluded that PPA "does not possess significant anorexigenic potency," *60 28-Capsule Bottles*, 211 F. Supp. at 209. Dr. Silverman's article made no claims of specific amounts of weight losses associated with PPA (I.D. 92).

The hearing examiner in *Alleghany* also discussed excerpts from medical literature which stated that: PPA is "useful to kill the appetite" [Hirsh] [Hirsh had actually repudiated that statement by

[21] *But see United States* v. *60 28-Capsule Bottles, More or Less, Etc.*, 211 F. Supp. 207 (D. N.J. 1962), *aff'd*, 325 F.2d 513 (3d Cir. 1963).

[22] *Id.*, n. 20.

the time of the Alleghany trial, see I.D. 92], 75 F.T.C. at 1009; "used . . . to depress appetite" [Grollman], *id.;* "employed . . . as an anorexiant" [Merck Index], *id.*, at 1010; listed with amphetamines as an appetite depressant [Leake], *id.;* less effective than amphetamines in the control of obesity [Sollmann], [20] *id.;* used in controlling appetite [Drill], *id.*, at 1011; "sometimes used to reduce appetite" [Laurence], *id.*, or is used for obesity [Remington's], *id.* No dosages are mentioned, no statements as to the effectiveness of PPA in appetite suppression are made (other than "useful"), no tests of the product in obesity control are mentioned; and no mention of weight losses of any degree appear in the discussion of this literature. *See* I.D. 70. Respondents also mention literature by "Kalb." We find no reference to Kalb in *Alleghany.*

None of this discussion supports the conclusion that "substantially all users of X-11 tablets will lose a significant amount of weight," since no weight losses are quantified and it is not clear whether weight losses of any quantity might be achieved by "substantially all" users of PPA in the dosages provided in X-11 tablets.

These various suggestions of PPA efficacy were placed in proper perspective by the testimony of several experts, including those of respondents. For example, Dr. Fineberg had never used PPA in his practice and could not say whether PPA would be effective in a 25 mg. dosage for the "normal run of people" (I.D. 90). Dr. Silverman made no claims "of specific amounts of weight loss associated with" PPA (I.D. 92). He did say that 75 mg. of PPA per day used in conjunction with a 1,200 calorie per day diet would bring about a significant decrease in weight in time (I.D. 93), but in a four-week study he performed with two groups on such diets, one using PPA and the other a placebo, the difference was a loss of only one-half or less than one-half pound per week, which, according to other testimony, is "clinically trivial" in obese persons, and, as the law judge found, "particularly in the absence of evidence that such loss can be continued" (I.D. 101-109). Dr. Hoebel, who also testified for respondents, also did a four-week study of the effectiveness of PPA, and also found a loss of a fraction of a pound per week associated with PPA (I.D. 118). That study was also criticized by complaint counsel's expert witnesses (I.D. 119-122), and Dr. Hoebel himself wrote that his "evidence for a statistically significant weight loss in a two-week period does not mean that this rate of loss would be continued over longer periods" (I.D. 120). [21]

The two 1957 FDA letters suggest that FDA permitted an "indications for use" labeling on a PPA product to read "useful as an appetite suppressant in the *dietary* management of obesity" (emphasis added). Like the other information in respondents' possession, these letters do not establish that significant weight losses may be achieved with PPA, with or without dieting.

Like Porter & Dietsch, Pay'n Save did not test X-11 and has done no research in medical literature as to its effectiveness. Pay'n Save "looked at, but did not critically examine" X-11 advertising, read the "plan," noted that the product was similar to others on the market, and assumed that the product must perform as advertised (RB 5-6).[23] We find that Pay'n Save, like Porter & Dietsch, had no substantiation whatever for the claim that "substantially all users of X-11 tablets will lose a significant amount of weight" at the time Pay'n Save disseminated X-11 advertising.

We conclude that respondents' advertising is false and misleading, because it implicitly represents that "substantially all users of X-11 tablets will lose a significant amount of weight" and that respondents possess competent scientific evidence supporting that claim, even though respondents did not have a reasonable basis for making such a claim at the time the advertising was disseminated. [22]

Failures to Disclose Material Facts

The complaint also alleges that respondents' advertisements were false because, in the words of the relevant statute, they "failed to reveal facts material in the light of [the] representations [made] or material with respect to consequences which may result from the use of the commodity to which the advertisement related under the conditions prescribed in said advertisement, or under such conditions as are customary or usual." The three alleged non-disclosures are: that the typical and ordinary experiences of consumers do not parallel the experiences reported in testimonials appearing in the advertisements (¶11); that a highly restricted caloric diet is a part of the X-11 plan (¶13); and that persons with high blood pressure, heart disease, diabetes or thyroid disease should only use X-11 tablets as directed by a physician (¶12). The ALJ found that all three of these non-disclosures violate the FTC Act. (I.D. 125-140)

We affirm all three of these conclusions.

Testimonials Respondents are charged with having failed to disclose material facts concerning testimonials used in their advertising, namely, the "typical or ordinary experience" of users of X-11 (¶11), making the advertising misleading (¶14). The ALJ found that respondents advertised testimonials proclaiming "I LOST OVER

[23] Pay'n Save also relied on the reputation of a manufacturer's representative, the fact that others advertised X-11, a Pharmacy Supervisor's recollection that he had been told in pharmacy school that PPA has been used as an appetite suppressant, and the fact that no consumer complaints were received (RB 16-17).

40 LBS.," "I LOST 80 LBS!" and others (I.D. 125). The smallest weight loss advertised is 40 pounds; the highest, 83 pounds (I.D. 126). He found that, by such representations, and other statements in the advertising, respondents left the impression that such large weight losses are typical with X-11 use. Testimonials of ordinary consumers were presented accompanied by statements such as "from Georgia to Nebraska to California American women have found a way that really helps off that ugly fat" (I.D. 126); "amazingly easy," "extraordinary simple" [sic], "more easily than you ever dreamed possible" (I.D. 12); and "RESULTS ARE GUARANTEED" (I.D. 12). [23]

The challenged testimonials did not appear in isolation and we have not read them that way. They were part and parcel of advertisements which, as we have found, claimed by implication that substantially all users of X-11 tablets would lose a significant amount of weight. The testimonials both fed this claim and drew sustenance from it. The net impression, as the ALJ found, is that the testimonials conveyed the message that extraordinarily large weight losses were typical or ordinary.

In fact, it is extremely rare for obese individuals to lose as much weight as depicted in the ads. (I.D. 126-129)

Restricted Diet For reasons that are apparent and that have already been mentioned (pages 8-9 above), we affirm the ALJ's findings and conclusions that respondents violated the FTC Act by failing to disclose that a highly restricted caloric diet is part of the X-11 regimen. Indeed, respondents concede that if their advertising is construed to promise weight reduction without dieting, as we find it did, then such a representation is false.

Safety of X-11 The final failure-to-disclose allegation concerns the safety of using X-11 tablets. An insert accompanying each package of X-11 tablets contains the following advice: "CAUTION: Individuals with high blood pressure, heart disease, diabetes or thyroid disease should use only as directed by a physician. . . ." The veracity of this warning is not disputed but the complaint challenged its sufficiency. The ALJ found that the failure of respondents to disclose these potentially hazardous consequences in their advertisements constituted false advertising (I.D. 139).

A majority of the Commission[24] agrees and adopts the ALJ's findings on this issue (I.D. 130-139). Respondents made strong, affirmative claims for their product. By failing to disclose in advertising that potentially serious health risks are associated with the use of X-11 they deprive consumers of an important and

[24] Commissioners Collier and Clanton dissent from the Commission's decision on this issue for the reasons set forth in Commissioner Collier's separate views.

material fact. The Commission finds this failure violates the letter and spirit of Section 12, and thereby Section 5. [24]

Defenses

Liability of Joseph Furth and Pay'n Save Two of the respondents, Joseph Furth and Pay'n Save object to their liability for the false advertising.

Mr. Furth objects to one of the ALJ's findings that he formulated, directed, and controlled the practices we find unlawful (RB 35). Paragraph 1 of the complaint charged that Furth "formulates, directs and controls certain acts and practices of [Kelly Ketting Furth, Inc.], *including the acts and practices hereinafter set forth*" (emphasis added). Furth's answer admits that he "formulates, directs and controls certain of its acts and practices." The Commission's Rules of Practice and Procedure provide that:

> An answer in which the allegations of a complaint are contested shall contain . . . specific admission, denial, or explanation of each fact alleged in the complaint or, if the respondent is without knowledge thereof, a statement to that effect. *Allegations of a complaint not thus answered shall be deemed to have been admitted.*

(Emphasis added.) 16 C.F.R. 3.12(b)(1)(ii). In view of the complaint's allegation, Furth's answer, and by operation of the rule, the ALJ was clearly correct in relying on the pleadings in his finding that Furth "is among those responsible for the formulation, direction and control of its acts and practices, including those alleged in the complaint." While the respondents as a group denied most of the allegations of unlawful conduct, Furth, by his answer, admitted his personal involvement for his principal, Kelly Ketting Furth, Inc., in the conduct that was subject to challenge.

Moreover, Furth does not contest Finding 143 which points to the same conclusion as the finding he challenges.[25] Furth's active role in formulating the advertising is not diminished, as respondents imply (RB 35-36), because he was "merely an employee" (a vice-president) of Kelly Ketting Furth or had to clear the initial acceptance of the Porter & Dietsch account with someone else. [25]

There is no dispute that Pay'n Save had no role in preparing X-11 advertising, but it did disseminate, in its own name, advertisements provided by Porter & Dietsch, either directly, or by paying for the placement of ads sent to news media by Porter & Dietsch (I.D. p. 106). Pay'n Save contends that it should not be held to an order because,

[25] *See also* respondents' "Answers to Request for Admissions," November 8, 1975, at 6, responding to complaint counsel's request for admissions of October 21, 1975, at 4.

as a retailer disseminating advertising prepared by another, it had no way of verifying the claims it was disseminating.

We find that Pay'n Save has violated Section 12 of the FTC Act, as alleged in the complaint. Section 12 provides that it is "unlawful for any person, partnership, or corporation to *disseminate, or cause to be disseminated,* any false advertisement . . . for the purpose of inducing, or which is likely to induce, directly or indirectly the purchase of food, drugs, devices or cosmetics . . ." (emphasis added).

We find that X-11 advertisements are "false advertisements" under Section 15,[26] and there can be no dispute that, by placing X-11 advertising, Pay'n Save "disseminated" it.[27] Section 12 does not provide any exemption for retailers who receive the advertisements they disseminate from others.[28]

It would appear to be no accident that Section 12 does not contain such an exemption. In Section 14, Congress attempted to deter the false advertising of food, drugs, devices, and cosmetics hazardous to consumer health (a subset of advertising prohibited by Section 12) by making it a misdemeanor to [26] disseminate such advertising with the intent to defraud or mislead. That section does not apply to any "publisher," radio-broadcast licensee, or agency or medium for the dissemination of advertising," in order to "avoid unwarranted hardship on the person who has conducted his business with proper prudence," H.R. Rep. No. 1613, 75th Cong., 1st Sess. 7 (1937). In hearings on predecessor legislation, Congress heard testimony to the effect that the media (like retailers, in the view of Pay'n Save) could not realistically test the veracity of claims they disseminated.[29] However, the "manufacturer, packer, distributor, or seller of the commodity to which the false advertisement relates" is expressly denied the exemption. The unmistakable implication is that such

[26] Although the ALJ did not find that Pay'n Save either disseminated the advertising in commerce or disseminated advertising for the purpose of, or which was likely to, induce purchases in commerce, with minor modifications we adopt complaint counsel's proposed finding 32, that Pay'n Save has caused X-11 advertising to be published in media of interstate circulation (and has therefore disseminated the advertising "in commerce"), which is supported by admissions and stipulations in the record and is uncontested. *See* Appendix.

[27] Counsel for Pay'n Save conceded as much at oral argument (Tr. of oral argument, p. 29).

[28] *Id.*, at 30.

[29] *See To Amend the Federal Trade Commission Act: Hearings on S. 3744 Before the Sen. Comm. on Interstate Commerce*, 74th Cong., 2d Sess. 68–69 (1936) (statement of C. B. Larrabee, representing the Legislative Committee of the National Publishers' Assn.); *Federal Trade Commission Act Amendments: Hearing on S. 3744 Before the House Comm. on Interstate and Foreign Commerce*, 74th Cong., 2d Sess. 68 (1936) (statement of William L. Daley, Washington Manager, National Editorial Assn.). Falsely advertised diet remedies were a specific concern. *See* 83 Cong. Rec. 415 (1938). A major impetus to the legislation was the Supreme Court's holding in *FTC* v. *Raladam Co.*, 283 U.S. 643 (1931), that the Commission had no jurisdiction to prevent, without a showing of injury to competition, the false advertising of a thyroid extract sold as a diet remedy. The predecessor legislation, S. 3744, 74th Cong., 2d Sess., did not incorporate language similar to that found in Sections 12–15; however, like Section 3 of the Wheeler-Lea Amendments (S. 1077, 75th Cong., 1st Sess., enacted as Pub. Law No. 447), the bill would have amended Section 5 to make it clear that false and misleading advertising ("unfair or deceptive acts or practices") is within the Commission's jurisdiction regardless of its effect on competition.

persons are subject to §12 as well as to Section 14. There can be no question that Pay'n Save is a "distributor" or "seller" of X-11. [27]

In light of the plain language of Section 12, we decline to adopt Pay'n Save's "flexible standard" of Section 12 liability, which would require us to except all but those who were "principals" in the preparation of advertising copy.[30] As Pay'n Save admits, nothing in the legislative history of Section 12 supports such an exception.[31] Moreover, we think it is not unreasonable for Congress to impose higher obligations on disseminator-distributors of advertising for food, drugs, (medical) devices, and cosmetics (items which may carry a potential for injury to health and safety).[32]

Nor do we consider this result harsh in the circumstances. Pay'n Save is a substantial company operating 140 retail stores, 92 of which are drug stores (RB 2). It runs only 30 or 40 advertisements prepared by its suppliers (Tr. 514, 566). Pay'n Save "looked at, but did not critically examine" X-11 advertising and reviewed the package insert revealing the "plan" (Tr. 531, 561). If Pay'n Save had critically examined the advertising in light of the package insert, it should have been obvious that the advertising at least did not coincide with the plan.

Collateral Estoppel As we have noted above in discussing the falsity of respondents' advertising, this is not the first occasion on which the Federal Government has challenged conduct of sellers of products containing PPA sold as a weight reduction preparation. *See Alleghany, supra,* at 15; *Hanover House, supra,* n. 19 at 16; and *60 28-Capsule Bottles* ("Unitrol"), *supra,* n. 21 at 18. In addition to asserting that these cases (except the Unitrol decision) support the truth of their advertising claims, respondents argue that they collaterally estop the Commission from a finding of liability in this case as to ¶¶9A and B, 10A and B, and 12 of the complaint. [28]

We reject this argument for several reasons. First, the truth of these respondents' advertising claims were simply not litigated in those proceedings. Moreover, the Commission decision to which we are referred was not a final adjudication but was, instead, dismissed without prejudice after the ALJ concluded that other challenges to other advertisements had not been established by a preponderance of the evidence. There can be no bar of collateral estoppel on these facts.[33]

[30] We intimate no view on the question whether or under what conditions such an approach would be appropriate under Section 5 of the FTC Act.

[31] Tr. of oral argument, at 29–31. *See also Mueller* v. *United States*, 262 F.2d 443, 446 (5th Cir. 1958) ("The term 'cause' is in the statute without any qualification relating to the advertiser's state of mind.").

[32] *See* Prosser, *Torts* 653–654 (4th Ed. 1971).

[33] Because the doctrine of collateral estoppel does not apply where different issues are tried, where different legal standards are applied, or where a dismissal without prejudice terminates the earlier litigation [*see George H.*

(Continued)

Location and Scheduling of Hearings The hearings were held in Seattle and Washington, D.C. on eight days between January 7, and January 26, 1976 (I.D. p. 7). In orders of December 3, 19, and 30, 1975, the law judge established the hearing sites and the hearing schedule. He noted that no one place was wholly satisfactory, because the witnesses to be called were dispersed into a number of locations, including Anchorage; Seattle; the San Francisco area; Los Angeles; Radnor, Pennsylvania; Minneapolis; Chicago; Miami; Boston; Baltimore; New York; and Princeton, New Jersey. The two individual respondents were located in St. Paul and Chicago, and all counsel in the proceeding were located in either Washington, D.C. or Seattle.[34]

[29] Respondents do not contend that their defense was impaired by the location or scheduling of the hearings, nor would the record support that claim.[35] Instead, they refer to the inconvenience encountered by the individual respondents in traveling to Washington, D.C. to testify (RB 2; RRB 9). However, in response to complaint counsel's motion to designate Seattle and Washington, D.C. as hearing sites, respondents' counsel expressed a willingness to designate "Chicago, Illinois, or, in the alternative, Washington, D.C."[36] Respondents cannot now contend that Washington, D.C. was an "inconvenient" location.[37]

[30] Respondents also argue that the complaint must be dismissed because complaint counsel did not prove that the hearing schedule was expeditious before the hearings took place, whether or not, in hindsight, the hearings were in fact expeditious (RRB 6), relying on *Universe Chemicals, Inc.*, 75 F.T.C. 1069 (1969). *Universe Chemicals* was decided when Section 3.41(b) of the Commission's Rules allowed the designation of multiple hearing sites only "in unusual and exceptional circumstances for good cause stated on the record."

Lee Co. v. *FTC*, 113 F.2d 583, 585 (8th Cir. 1940); *United States* v. *Willard Tablet Co.*, 141 F.2d 141, 143 (7th Cir. 1944); *Hastings Mfg. Co.* v. *FTC*, 153 F.2d 253, 255 (6th Cir. 1946)], we need not delve the legal question of the extent to which an administrative agency in pursuit of the public interest such as the Commission is bound by that doctrine, or whether an earlier finding that rests on then-current technical and scientific knowledge, once made, is insulated from later challenges based on new evidence or later developments and discoveries.

[34] "Order Directing Hearings in Seattle and Washington, D.C.," December 3, 1975, at 2.

[35] For that reason, *Jeffries* v. *Olesen*, 121 F. Supp. 463 (S.D. Calif. 1954) is inapposite. There a respondent in a Post Office proceeding had no funds to appear at a hearing in Washington, D.C. and was unable to present his defense.

[36] "Answer to Complaint Counsels' Motion to Designate Seattle and Washington, D.C. as the Locations for Hearings," November 18, 1975, at 10. Counsel for Pay'n Save Corporation concurred in that pleading, "Revised Statement of Pay'n Save Corporation with Respect to Location of Hearings," November 26, 1975, at 1.

[37] In choosing a hearing site, the ALJ was obligated to consider the convenience of the agency in addition to the convenience of respondents, because the term "parties" in the Administrative Procedure Act, 5 U.S.C. 554(b), 555(b), includes agency parties. *Maremont Corp.* v. *FTC*, 431 F.2d 124 (7th Cir. 1970); *Burnham Trucking Co.* v. *United States*, 216 F. Supp. 561 (D. Mass. 1963); Sen. Rep. No. 752, 79th Cong., 1st Sess. 17 (1945). Respondents also offer us a chart which purports to show that the total air miles traveled by all participants in the hearings were 22 percent greater than they would have been if all hearings had been held in Chicago or Washington, D.C. (RB, "Appendix A-1"). We do not see the relevance of this calculation to either the expeditiousness of the hearings or to the convenience of respondents.

Under the current rule, promulgated well before this proceeding began, 37 F.R. 5609 (1972), there is no longer any such requirement. In this case, the hearings were expeditious, consuming only 8 days over a three-week period.

We conclude that the ALJ did not abuse his discretion, and respondents have not been prejudiced in any cognizable way by the location or scheduling of the hearings.

Miscellaneous Objections Respondents also contend that they were misled by the ALJ and by complaint counsel's "shifting position" on the relevance of the efficacy of PPA (RB 29-30; RRB 30-32). We find it hard to believe that respondents were unfairly confused by the discussions among counsel and the ALJ which are cited to us. As the ALJ pointed out, it was not the efficacy of PPA *per se* that was put in issue by the Commission's complaint, but rather the veracity of X-11 advertising claims. The efficacy of PPA was deemed relevant only insofar as it is an ingredient of the product for which claims are made.

Moreover, the alleged prejudice is that, after respondents' counsel understood the issue "it was . . . too late to cross-examine Drs. Margen and Drenick on the 'degree of effectiveness' [of PPA]" (RB 29). But respondents did in fact cross-examine Dr. Margen extensively as to his views on the effectiveness of PPA (see Tr. 294-326), including cross-examination as to his interpretation of a study by Dr. Hoebel, on which respondents rely to establish the effectiveness of PPA. Respondents also cross-examined Dr. Drenick as to the sufficiency of studies and medical literature concerning the efficacy of PPA (Tr. 466-476). Respondents [31] had ample opportunity to present evidence and testimony concerning the efficacy of PPA insofar as it related to their advertising claims, and they did so. Indeed the purported efficacy of PPA in suppressing appetite was the cornerstone of their defense. There has been no error. *Murray Space Shoe Corp.*, 59 F.T.C. 803, 828-829 (1961), *aff'd*, 304 F.2d 270 (2d Cir. 1962); *Trade Union Courier Publishing Corp.*, 51 F.T.C. 1275, 1295 (1955). Finally, since respondents failed to request that Drs. Margen or Drenick be recalled once the scope of the inquiry was clarified in their minds, they waived any claim of error.

Respondents next argue that the proceedings against them are not in the public interest since others are engaged in similar practices. We are told that consumers with a proclivity for purchasing deceptively advertised weight reduction preparations will still be able to satisfy their demand.

We reject this variation on the old theme of selective enforcement. Official proceedings against law violators could seldom, if ever, be

brought were such a theory to be approved. Rules of conduct adopted by governments are seldom self enforcing and seldom obeyed universally. Detection and apprehension of all violators simply cannot be a precondition to the prosecution of each violator. Moreover, proceeding against all violators would be an illusory solution to this perennial dilemma since someone not currently a violator might become one tomorrow.[38]

[32] In addition to these objections, respondents argue that the delays encountered in investigating and challenging their advertising claims demonstrate a lack of public interest in these proceedings. In our opinion, this contention is without legal force.[39] It is directed basically at the wisdom of expending limited public resources to correct particular law violations, a decision that is committed to the Commission's discretion. That bridge was crossed for the last time over two years ago when the Commission issued the complaint in this case.[40]

At oral argument, respondents raised a number of additional objections: that the Commission had no "reason to believe" that Kelly Ketting Furth and Joseph Furth had violated the FTC Act at the time the complaint issued (Tr. 5-6)[41]; that a news release announcing issuance of the complaint caused some Porter & Dietsch customers to cancel orders (Tr. 6, 14); that respondents had an inadequate opportunity to negotiate a consent settlement (Tr. 6, 10); and that the law judge was biased (Tr. 6, 19). None of these objections has any merit. [33]

The complaint itself set forth the basis for the Commission's reason to believe that a law violation had occurred and that a proceeding would be in the public interest. The complaint was clearly adequate in all respects and the allegations were fully and fairly adjudicated. There was no need to try the issuance of the complaint itself or to adjudicate the investigation that preceded it.

At least some incidental individual loss is unavoidable when public rights are adjudicated, as they must be, in public forums. *FTC* v. *Cinderella Career and Finishing Schools, Inc.*, 404 F.2d 1308, 1312-1316 (D.C. Cir. 1968). There is no suggestion that the press releases announcing the initiation of this action were factually incorrect or

[38] Under 15 U.S.C. 45(m), the Commission is free to hold other concerns to the same standards we are imposing on these respondents, when the order we will enter becomes final.

[39] The existence of prior investigations which were not pursued is no bar to this action. *See Parke, Austin & Lipscomb* v. *FTC*, 142 F.2d 437, 441 (2d Cir. 1944).

[40] For the same reason, we decline to dismiss this proceeding simply because X-11 tablets are relatively inexpensive, selling for $3.00 or $5.00 a box, and because consumers may be able to discern the efficacy of the product by using it. (*See*, RRB 16-17).

[41] No facts are cited in support of the allegation, although at oral argument counsel did mention that he had refused to respond to questions concerning Kelly Ketting Furth and Joseph Furth before the complaint issued (Tr. 11).

that they evidenced prejudgment or bias on the part of the Commission. We therefore decline to disturb our earlier rulings on respondents' interlocutory motions regarding the press releases, 86 F.T.C. 896, 1570 (1975).

Respondents concede that the Commission's staff engaged in consent negotiations with them before the complaint issued, but, after "about 14 telephone calls,"[42] the parties could not agree. Of course, respondents could have engaged in consent negotiations after the complaint issued if they had wished, and under the Commission's Rules of Practice, 16 C.F.R. 3.25, could have unilaterally offered the Commission a consent order which would present a "likelihood of settlement." Respondents simply have not been denied the opportunity to settle this matter.

The evidence presented to demonstrate the ALJ's alleged "bias" is one passage of the initial decision, at 94, where he read *Stauffer Laboratories, Inc.* v. *FTC*, 343 F.2d 75 (9th Cir. 1965) as indicating that Stauffer had relied on *Carlay* on appeal. Respondents point out that there is no mention of *Carlay* in the court's decision.[43] The finding will be [34] modified to correct the ALJ's error, *infra*. However, we fail to see how his mistake evidences "bias," nor do respondents provide any authority in support of their contention.[44]

Relief

The ALJ has proposed a cease and desist order substantially similar to the detailed notice order attached to the Commission's complaint. We will revise the order in conformity with this opinion and to prevent problems of enforcement which reside in the wording of some of its provisions.

We first consider the product coverage as to the various respondents. We believe the proposed order as to Porter & Dietsch and William H. Fraser is too narrow in scope. The first paragraph of the order would only apply to the advertising of X-11 tablets, preparations of "similar composition or similar properties," or dietary aids "containing phenylpropanolamine." Although X-11 represents the bulk of Porter & Dietsch sales (I.D. 1), we find that Porter & Dietsch is "continuously trying new products" (Tr. 765), and has marketed a

[42] Tr. of oral argument at 10.

[43] The opinion does indicate that Stauffer argued that the Commission had to consider a vibrating couch an inextricable part of the Stauffer reducing "plan" as a matter of law, 343 F.2d at 78.

[44] We also reject respondents' contentions, at RB 35-58, that the ALJ's findings in any way bespeak "bias" or "prejudice." The only "bias" cited is his rejection of respondents' position. Finally, we reject respondents' contention (RB 58) that they have been denied adequate time and appeal brief pages (in excess of the limits imposed by the Commission's Rules of Practice). Respondents were given an extension of 20 days to file their appeal briefs and together filed a total of 163 pages of argument and other materials.

number over the years (Tr. 754-766, 817-819), including another diet "plan" (Tr. 758).[45] Porter & Dietsch, as a wholesale operation securing its products from others (I.D. 1, 9; Tr. 766), is not faced with the expense of modifying manufacturing facilities as new products are added to its line. Porter & Dietsch and William H. Fraser have been marketing X-11 for years, first disseminating X-11 "plan" advertising in July, 1968 (Tr. 932-939). [35]

The practice of deceptively advertising a diet remedy, with or without a "plan," is not uniquely suited to products containing PPA or ingredients of "similar composition or similar properties." As we have seen, deceptions involving diet remedies have related to a wide variety of foods, drugs, devices, and cosmetics, the common thread being that human vanity and concern for health, and the inability to cope with the self-discipline of dieting, are preyed upon by making promises which cannot be kept.[46] Finally, we note that Mr. Fraser and wholly-owned subsidiaries of Porter & Dietsch have run afoul of our statute before.[47] For these reasons, we will enter an order as to Porter & Dietsch and William H. Fraser covering any "food," "drug," "cosmetic" or "device," as these terms are defined by the Federal Trade Commission Act.

For similar reasons, the product coverage of those provisions of the order pertaining to Kelly Ketting Furth or Joseph Furth should not be limited to X-11 or dietary aids containing PPA. Kelly Ketting Furth and Joseph Furth have handled X-11 advertising since its inception, and played an active role in its development and dissemination. Advertising agencies are even less restricted in their ability to use similar deceptive practices in connection with other products than wholesale and retail distributors. Particularly mindful of Mr. Furth's open acknowledgement that "the pills will not reduce weight an iota" (CX 164), we find that an order applicable to all diet remedies should be entered against Mr. Furth and Kelly Ketting Furth. [36]

Finally, we reject Pay'n Save's contention that the order as to it should be confined to the advertising of X-11 tablets alone, and "should recite that Pay'n Save's lack of knowledge of, or reason to know of, the falsity or deception of any future ad will be a defense to

[45] It is not clear whether this product would be covered by the ALJ's proposed order or not, because the record does not reveal the product's composition.

[46] *See* n. 8, *supra* at 10.

[47] *Udga, Inc., and William Fraser and Mary Fraser*, F.T.C. Dkt. 2830, 24 F.T.C. 1245 (1937) (antacid deceptively advertised as a cure for ulcers) (Tr. 754). Mr. Fraser is also subject to a Commission consent order, *Ru-Ex, Inc.*, F.T.C. Dkt. C-1, 59 F.T.C. 839 (1961), which we do not consider in "aggravation," *ITT Continental Baking Co., Inc. v. FTC*, 532 F.2d 207, 223 (2d Cir. 1976), but in possible "mitigation" of the need for a broad order in this instance. We find that that order would not apply to diet remedies, since it is limited to products similar to the one sold as an arthritis or rheumatism remedy in that case.

any future charge" (RB 26). There is no such defense to Section 12 of the FTC Act and it would therefore be inappropriate to write such a defense into the order. Moreover, we believe that the order coverage should be expanded to include any food, drug, cosmetic, or device held out as a diet remedy As we have noted, X-11 is not a product uniquely suited to the dissemination of false advertisements promising weight loss. Pay'n Save has carried "several similar products" for many years (Tr. 507), and as a chain store retailer, Pay'n Save can easily shift its product lines.[48] Pay'n Save could as easily decline to examine "critically" the advertising copy of other distributors of diet remedies.[49] Finally, we note that Pay'n Save has been advertising X-11 since 1969 or 1970 (Tr. 508). We are not dealing with an isolated incident. These factors, and the apparent attraction in deceptively advertising diet remedies, exhibited by the Commission's experience of over 50 years in finding innumerable variations of this deception, *supra*, n. 8 at 10, justify a comprehensive order.

In short, we conclude that the order should not be limited to X-11, products of similar composition, or those containing PPA. We will enter an order as to Kelly Ketting Furth, Mr. Furth and Pay'n Save, applying to the advertising of any food, drug, cosmetic or device held out as a diet remedy. As to Porter & Dietsch and William H. Fraser, the order will apply to any food, drug, cosmetic or device.

These changes in product coverage will also apply to the constraints on the use of testimonials or claims of unique ingredients. We have further modified the order provision concerning testimonials so as simply to prohibit [37] respondents from representing directly or by implication that the testimonial reflects the typical experience of users of the product unless, in fact, it does. In addition we would observe that even where respondents do not represent that a testimonial reflects the typical experience of users, respondents may not employ testimonials which reflect the unusual experience of a tiny minority to suggest that a product is generally efficacious, when in fact it is not. To underscore this point, we have expressly noted in order paragraphs I A. and I B. that testimonials, among other devices, may not be used to effect the misrepresentations prohibited by those paragraphs.

We think the proposed order provision, however, is unnecessarily broad. To prevent further deception as to the need to adhere to a

[48] Pay'n Save sells "literally thousands of products" (RRB 15), and disseminates 30 or 40 advertisements prepared by its suppliers (Tr. 514, 566). The record does not reveal how many of these 30 or 40 products are foods, drugs, cosmetics or devices sold as diet remedies.

[49] *See generally* Tr. 501-577. *See also Kraftco Corp.*, F.T.C. Dkt. 9035, 89 F.T.C. 46 (1977), 3 CCH Trade Reg. Rep. ¶21,263 at p. 21,170 n. 6, *appeal pending*, No. 77-4078 (2d Cir.); *Tashof v. FTC*, 437 F.2d 707, 715 (D.C. Cir. 1970).

restricted diet we will prohibit respondents from representing directly or by implication that the testimonial is the typical experience of users of the product unless, in fact, the testimonial is the typical experience of the users of the product.

Finally, we find four order provisions to be unnecessary or somewhat misdirected. First, the ALJ proposes to prohibit further unsubstantiated diet remedy advertising with an order provision applying to X-11 or "any other product potentially affecting human health or safety" and requiring "adequate, well-controlled scientific tests accepted as such by the Federal Trade Commission" as substantiation for efficacy claims. The substantiation, including the "original data" supporting any tests, would have to be furnished to the Commission in advance "as documents available for public inspection," and copies of summaries of the test results and methodologies employed would have to be made available through the mail on request. The availability of the summaries would have to be disclosed clearly and conspicuously in advertising (I.D. p. 112-113).

We have eliminated the requirements that respondents pre-clear their substantiation materials with the Commission before disseminating them to the public and that they prepare and distribute summaries of such materials. Although respondents have made little effort to substantiate their claims, we doubt that a pre-clearance procedure for their future advertising copy is needed or desirable, and we doubt that most consumers would care to see the details of respondents' substantiation. More probably, consumers would prefer to be in a position to rely on the advertising claims without the trouble and expense of investigating the substantiation for themselves. Therefore, we believe that it would [38] be sufficient to require adequate substantiation for advertising claims and to require respondents to submit compliance reports for five years, so that the Commission can assure itself, in light of respondents' past disregard for the requirements of our statute, that the order is being obeyed. The order will be modified accordingly.

Second, the proposed order would also require respondents to reveal the amount of weight loss, on a "per-week basis" that might be expected from the use of X-11 or similar products, based upon "adequate, well-controlled scientific tests" if weight loss is advertised as a result of use of the products (I.D. pp. 114-115). As the record indicates, "per-week" weight losses may be deceptive because initial weight losses in the course of a dietary regimen generally are not sustained for an extended period (I.D. 68, 76-77, 83, 95, 107, 120). In addition, we believe that a requirement that respondents possess

adequate substantiation for their advertising claims including general claims will suffice to correct the deceptions we have found. We will therefore omit this provision from the order.

Third, the ALJ proposes that the Commission require an affirmative disclosure of the need to diet, the lack of evidence that significant or lasting weight losses will be assisted, and the FDA-mandated label warning in all advertising of X-11 or similar products. We agree that, to prevent further deception, consumers should be told that X-11, products of similar composition, and products containing PPA (or methylcellulose) will not assist in weight loss without adherence to a restricted diet, and may not in any way promote significant or lasting weight losses. Any advertising of such products as diet remedies without affirmative disclosure of these facts would be misleading to consumers, who, as we have found, may be expected to purchase diet remedies to avoid the self-discipline of low-[39]calorie diets. The mere holding out of such products as diet remedies without these disclosures would therefore be misleading.[50] A majority of the Commission[51] also agrees that future advertising for X-11 or similar products should warn of the health risks associated with its use. However, it believes a disclosure less lengthy than the FDA-mandated warning will provide consumers with adequate notice. The order provision is accordingly modified.

Fourth, the ALJ would also prohibit respondents from "attempting to mislead or misleading the public that a 'plan,' 'regimen' or 'program' is being offered when in truth respondents are simply marketing X-11 tablets, or one of the foregoing preparations, products, or aids" (I.D. p. 115). The deception is not in the offering of a "plan," but in the failure to disclose that the "plan" involves a stringent diet. We will enter an order requiring disclosure of the need to diet and will omit the ALJ's proposed order provision.

We find that the other provisions of the order that the ALJ recommends are necessary and appropriate to insure that false and deceptive advertising is recalled and ceased.

An appropriate order is appended.

FINAL ORDER

This matter having been heard by the Commission upon the appeal of respondents from the initial decision, and upon briefs and

[50] Should the state of medical knowledge change and provide support for the efficacy of such products, respondents will, of course, be free to petition the Commission for a modification of the order under Section 3.72 of our Rules.

[51] Commissioners Collier and Clanton dissent from the Commission's decision on this issue for the reasons set forth in Commissioner Collier's separate views.

oral argument in support thereof and opposition thereto, and the Commission for the reasons stated in the accompanying Opinion having determined to sustain the initial decision with certain modifications:

It is ordered, That the initial decision of the administrative law judge, pages 1-111, be adopted as the Findings of Fact and Conclusions of Law of the Commission, except to the extent modified or otherwise indicated in the accompanying Opinion. [2]

Other Findings of Fact and Conclusions of Law of the Commission are contained in the accompanying Opinion.

It is further ordered, That the following order to cease and desist be, and it hereby is, entered:

ORDER

I

It is ordered, That respondents Porter & Dietsch, Inc., a corporation, its successors and assigns, and its officers, and William H. Fraser, individually and as an officer of said corporation; and the agents, representatives and employees of the foregoing respondents, directly or through any corporation, subsidiary, division or other device, in connection with the advertising, offering for sale, sale, or distribution of any "food," "drug," "cosmetic" or "device" (as these terms are defined in the Federal Trade Commission Act) in or affecting commerce as "commerce" is defined in the Federal Trade Commission Act, shall forthwith cease and desist from:

A. Representing orally, in writing, or in any manner, directly or by implication, including through the use of testimonials that a user of such a product can lose weight without restricting his or her accustomed caloric intake or while he or she continues to eat the foods of his or her choice (or words or depictions of similar import or meaning);

B. Representing orally, in writing, or in any manner, directly or by implication, including through the use of testimonials that a user of such a product can achieve any result, unless at the time such representation is made it is fully and completely substantiated by competent scientific or medical tests or studies, with the results of the tests or studies, the original data collected in the course of the test or study (if performed by or at the request of or with financial assistance from any respondent), and a detailed description of how the test or study was performed available in written form for inspection by the Federal Trade Commission for at least three years following the final use of the representation; [3]

C. Representing orally, in writing, or in any manner, directly or by implication, that any testimonial for any such product represents the typical or ordinary experience of members of the public who use the product unless this is the case.

D. Representing orally, in writing, or in any manner, directly or by implication, that any such product contains one or more unique ingredients or components, unless respondents can establish that any such ingredients or components are unavailable in products sold by others.

E. Disseminating or causing to be disseminated by United States mail or by any means in or affecting commerce, as "commerce" is defined in the Federal Trade Commission Act, any advertisement for any such product containing phenylpropanolamine hydrochloride or similar ingredients with similar properties, or methylcellulose (whether or not such products contain other ingredients as well) or any product held out as a diet remedy or other remedy for the reduction of human body weight unless such advertising "clearly and conspicuously" (in print at least as large as the largest print appearing in the advertising or, in an oral presentation, in speech as clear and distinct as that delivered in the rest of the presentation) discloses the following statements, with nothing to the contrary or in mitigation of these statements:

DIETING IS REQUIRED
and
WARNING: THIS PRODUCT POSES A SERIOUS HEALTH RISK FOR SOME USERS. READ THE LABEL CAREFULLY BEFORE USING.

[4] II

It is further ordered, That respondents Kelly Ketting Furth, Inc., a corporation, its successors and assigns, and its officers, and Joseph Furth, individually and as an officer of said corporation; and Pay'n Save Corporation, a corporation, its successors and assigns, and its officers, agents, representatives; and employees of the foregoing respondents, directly or through any corporation, subsidiary, division or other device, in connection with the advertising, of any "food," "drug," "cosmetic," or "device" (as these terms are defined in the Federal Trade Commission Act) held out as a diet remedy or other remedy for the reduction of human body weight, shall forthwith cease and desist from disseminating or causing to be disseminated by United States mail or by any means in or affecting commerce as "commerce" is defined in the Federal Trade Commission Act, any advertisement which contains a representation or testimonial for such product prohibited by Paragraph I of this order,

or which omits a disclosure for such product required by Paragraph I of this order.

III

It is further ordered, That each respondent forthwith deliver a copy of this order to each of its own operating divisions and subsidiaries, to all present and future personnel of respondents engaged in the preparation, creation or placing of advertising of foods, drugs or devices on behalf of respondents, and to all present and future agencies engaged in the preparation, creation or placing of such advertising for respondents, and that respondents secure from each such person and agency a signed statement acknowledging receipt of said order. [5]

IV

It is further ordered, That respondents immediately recall and retrieve, from all persons and entities that have engaged in the advertising or promotion of X-11 tablets within the past two years, all advertising mats and promotional material which contain a representation or testimonial prohibited by this order or which omit a disclosure required by this order. Respondents Porter & Dietsch, Inc., and William H. Fraser shall also deliver written notice of the requirements of this order to all distributors and retailers of products marketed by said respondents, and shall institute a program of continuing surveillance adequate to reveal whether they are complying with said requirements including the above recall provision. In the event that nonconformity with any such requirements is discovered, said respondents shall immediately cease supplying all products to said distributors or retailers until adequate, reliable assurance of conformity is obtained.

V

It is further ordered, That all respondents, their successors and assigns, shall maintain complete business records relative to the manner and form of their compliance with this order. Respondents shall retain each such record for at least three years, and shall retain for at least two years beyond the last dissemination of any representation or testimonial the documentation in support of and on which respondents relied in making such representation or testimonial. Upon reasonable notice, respondents shall make any and all such records available for inspection and photocopying by authorized representatives of the Federal Trade Commission at

respondents' place of business. For respondents Porter & Dietsch, Inc., and William H. Fraser, such records shall include (but not be limited to) all advertising, sales memoranda, the substantiation for all applicable advertising claims, correspondence with persons who place advertising, and other pertinent documents. [6]

VI

It is further ordered, That all respondents herein notify the Commission at least thirty (30) days prior to any proposed change in a corporate respondent, such as dissolution, assignment or sale resulting in the emergence of any successor corporation or corporations, the creation or dissolution of subsidiaries, or any other change in said corporations which may affect compliance obligations arising out of this order.

VII

It is further ordered, That each individual respondent named herein for a period of five (5) years from the effective date of this order promptly notify the Commission of the discontinuance of his present business or employment and/or of his affiliation with a new business or employment. If applicable each such notice shall include the respondent's new business address and a statement of the nature of the business or employment in which he is newly engaged as well as a description of his duties and responsibilities in connection with the business or employment. The expiration of the notice provision of this paragraph shall not affect any other obligation arising under this order.

VIII

It is further ordered, That the respondents herein shall, within sixty (60) days after service of this order, and annually for five years thereafter, file with the Commission a written report setting forth in detail the manner and form of their compliance with this order. The expiration of the obligation to file such reports shall not affect any other obligation arising under this order.

Separate Statement of Commissioner Calvin J. Collier in which Commissioner David A. Clanton Concurs

There are certain specific portions of the majority decision from which I dissent. They are footnoted in the decision. My reasons follow.

Safety of X-11 The majority affirms the ALJ's decision that

respondents' failure to include FDA's required label warning message in their advertising violated duties imposed by sections 5 and 12 of our statute.

There is little evidence in this record to distinguish this case from all others in which health warnings are required to be or are voluntarily placed on packaging but are absent from advertising. The ALJ found that certain of the contraindicated medical conditions for PPA occur more frequently and with greater severity among the obese and overweight than in the population generally (I.D. 136). However, the correlations were not quantified, and nothing else is revealed about the conduct or behavior patterns of this population in relation to OTC drug use in general or weight reduction preparations in particular.

In other contexts, we have recently determined to deal with the relationships between mandatory labeling and advertising disclosures through rulemaking.[1] In the absence of other circumstances, this approach has several important advantages. For example, it permits interested persons to comment on such issues as the comprehensibility of labeling requirements communicated through other media and the net incremental health benefits of advertising disclosures. Finally, PPA, the ingredient of X-11 which precipitated the package insert warning, is found in a variety of over-the-counter drugs including other weight reduction preparations [2] and common decongestants.[2] In sum, I do not believe this case provides a sound factual or jurisprudential foundation for the majority's holding.

APPENDIX

The Findings of Fact and Conclusions of Law set out in the Initial Decision of the administrative law judge are adopted by the Commission except to the extent they are qualified or supplemented in the Commission's Opinion and in the Appendix.

The following Findings in the Initial Decision are modified as indicated:

I.D. 44: After "Tiny Tablet" in the seventh line of the finding, add:

(CX 1, 2, 11, 35, 46-48, 50, 52, 56, 58, 61-62 ["X-11 is the PROVEN and SOUND method . . ."], 74, 79)

At the end of the finding, add:

Some advertisements referred to "clinic tested ingredients" (CX 47, 49, 74); or stated that "The X-11 Reducing Plan is medically recognized as an effective plan to lose ugly fat" (CX 74).

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[1] *See* Advertising for Over-the-Counter Drugs, 40 F.R. 52, 631 (1975); and Advertising for Over-the-Counter Antacids, 41 F.R. 14,534 (1976).

[2] Tr. of oral argument 46 (September 29, 1976). FDA is considering a monograph recognizing the drug as an effective nasal decongestant, 41 F.R. 38,400 (1976).

I.D. 60: Add, after "*supra*" in the last line, "and the following additional materials." Strike "(CX 122-26)" and substitute "(CX 122-130)." Substitute a colon for the period concluding the finding and add:

"(1) a hand-written statement that a Dr. Necheles believed that methylcellulose expands in the stomach (CX 125);
(2) a biographical sketch of Dr. Necheles (CX 126);
(3) a photocopy of a two-page statement edited by a Dr. Cyril Mitchell MacBryde, to the effect that obesity leads to increased mortality rates (CX 127);
(4) a photocopy of a two-page "product information" sheet from the Dow Chemical company describing its methylcellulose product, specifically how aqueous solutions of the product might be prepared, and describing the properties of such solutions (and mentioning that the product swells with hydration) (CX 128);
(5) a photocopy of two pages, one of which has been labeled, by hand, "U.S. Dispensatory," which indicates, among other things, that methylcellulose is "used as a laxative in chronic constipation," "imparts a sense of fullness in the patient," and "is sometimes employed in preparations intended to curb appetite in obese persons" (CX 129); and
(6) a photocopy of a letter dated February 24, 1969, from a "Butterfield Laboratories" which concluded that "methylcellulose when wetted does swell like a sponge" and that the 1967 edition of *Drugs of Choice*, edited by Walter Modell, indicated that "methylcellulose has been suggested as an appetite satiator for the treatment of obesity" (CX 130)."

Finally, add: "In addition, in his letter Mr. Gettleman mentioned two letters which FDA had written to other companies in 1957 concerning the labeling of products containing PPA, copies of which have been introduced into evidence as RX 16 and RX 17."

I.D. p. 94: Strike "relied on the *Carlay* case and" in the third line of the first full paragraph.

We make the following additional findings of fact:

In the course and conduct of its business, Pay'n Save has caused X-11 advertisements to be published in media of interstate circulation and has used means and mechanisms of interstate commerce in doing so (Admissions of Pay'n Save, Nos. 15 and 16b; Stipulations, Tr. 115-116, 377-380, 428-434; Answer of Pay'n Save, ¶6).

In the course and conduct of their business, Porter & Dietsch, Inc. and William H. Fraser cause advertisements for X-11 to be published in media of interstate circulation (Answer, ¶6, p. 7). They have used and continue to use means and mechanisms of interstate commerce in doing so (Admission No. 16a).

In the course and conduct of their business, Kelly Ketting Furth and Joseph Furth cause advertisements for X-11 to be published in media of interstate circulation (Answer, ¶6, p. 7). In doing so, they have used and continue to use means and mechanisms of interstate commerce (Admission No. 16c).

APPENDIX C — FIRST AMENDMENT TO THE CONSTITUTION OF THE UNITED STATES

Congress shall make no law respecting an establishment of religion, or prohibiting the free exercise thereof; or abridging the freedom of speech, or of the press; or the right of the people peaceably to assemble, and to petition the Government for a redress of grievances.

APPENDIX C — FIFTH AMENDMENT TO THE CONSTITUTION OF THE UNITED STATES

No person shall be held to answer for a capital, or otherwise infamous crime, unless on a presentment or indictment of a Grand Jury, except in cases arising in the land or naval forces, or in the Militia, when in actual service in time of War or public danger; nor shall any person be subject for the same offence to be twice put in jeopardy of life or limb; nor shall be compelled in any criminal case to be a witness against himself, nor be deprived of life, liberty, or property, without due process of law; nor shall private property be taken for public use, without just compensation.

APPENDIX C — THE FEDERAL TRADE COMMISSION ACT, 15 U.S.C. §45

§ 45. Unfair methods of competition unlawful; prevention by Commission—Declaration of unlawfulness; power to prohibit unfair practices

(a)(1) Unfair methods of competition in or affecting commerce, and unfair or deceptive acts or practices in or affecting commerce, are declared unlawful.

(2) The Commission is empowered and directed to prevent persons, partnerships, or corporations, except banks, common carriers subject to the Acts to regulate commerce, air carriers and foreign air carriers subject to the Federal Aviation Act of 1958, and persons, partnerships, or corporations insofar as they are subject to the Packers and Stockyards Act, 1921, as amended, except as provided in section 406(b) of said Act, from using unfair methods of competition in or affecting commerce and unfair or deceptive acts or practices in or affecting commerce.

Proceeding by Commission; modifying and setting aside orders

(b) Whenever the Commission shall have reason to believe that any such person, partnership, or corporation has been or is using any unfair method of competition or unfair or deceptive act or practice in or affecting commerce, and if it shall appear to the Commission that a proceeding by it in respect thereof would be to the interest of the public, it shall issue and serve upon such person, partnership, or corporation a complaint stating its charges in that respect and containing a notice of a hearing upon a day and at a place therein fixed at least thirty days after the service of said complaint. The person, partnership, or corporation so complained of shall have the right to appear at the place and time so fixed and show cause why an order should not be entered by the Commission requiring such person, partnership, or corporation to cease and desist from the violation of the law so charged in said complaint. Any person, partnership, or corporation may make application, and upon good cause shown may be allowed by the Commission to intervene and appear in said proceeding by counsel or in person. The testimony in any such proceeding shall be reduced to writing and filed in the office of the Commission. If upon such hearing the Commission shall be of the opinion that the method of competition or the act or practice in question is prohibited by sections 41 to 46 and 47 to 58 of this title, it shall make a report in writing in which it shall state its findings as to the facts and shall issue and cause to be served on such person, partnership, or corporation an order requiring such person, partnership, or corporation to cease and desist from using such method of competition or such act or practice. Until the expiration of the time allowed for filing a petition for review, if no such petition has been duly filed within such time or, if a petition for review has been filed within such time then until the record in the proceeding has been filed in a court of appeals of the United States, as hereinafter provided, the Commission may at any time, upon such notice and in such manner as it shall deem proper, modify or set aside, in whole or in part, any report or any order made or issued by it under this section. After the expiration of the time allowed for filing a petition for review, if no such petition has been duly filed within such time, the Commission may at any time, after notice and opportunity for hearing, reopen and alter, modify, or set aside, in whole or in part, any report or order made or issued by it under this section, whenever in the opinion of the Commission conditions of fact or of law have so changed as

to require such action or if the public interest shall so require: *Provided, however*, That the said person, partnership, or corporation may, within sixty days after service upon him or it of said report or order entered after such a reopening, obtain a review thereof in the appropriate court of appeals of the United States, in the manner provided in subsection (c) of this section.

Review of order; rehearing

(c) Any person, partnership, or corporation required by an order of the Commission to cease and desist from using any method of competition or act or practice may obtain a review of such order in the court of appeals of the United States, within any circuit where the method of competition or the act or practice in question was used or where such person, partnership, or corporation resides or carries on business, by filing in the court, within sixty days from the date of the service of such order, a written petition praying that the order of the Commission be set aside. A copy of such petition shall be forthwith transmitted by the clerk of the court to the Commission, and thereupon the Commission shall file in the court the record in the proceeding, as provided in section 2112 of Title 28. Upon such filing of the petition the court shall have jurisdiction of the proceeding and of the question determined therein concurrently with the Commission until the filing of the record and shall have power to make and enter a decree affirming, modifying, or setting aside the order of the Commission, and enforcing the same to the extent that such order is affirmed and to issue such writs as are ancillary to its jurisdiction or are necessary in its judgment to prevent injury to the public or to competitors pendente lite. The findings of the Commission as to the facts, if supported by evidence, shall be conclusive. To the extent that the order of the Commission is affirmed, the court shall thereupon issue its own order commanding obedience to the terms of such order of the Commission. If either party shall apply to the court for leave to adduce additional evidence, and shall show to the satisfaction of the court that such additional evidence is material and that there were reasonable grounds for the failure to adduce such evidence in the proceeding before the Commission, the court may order such additional evidence to be taken before the Commission and to be adduced upon the hearing in such manner and upon such terms and conditions as to the court may seem proper. The Commission may modify its findings as to the facts, or make new findings, by reason of the additional evidence so taken, and it shall file such modified or new findings, which, if supported by evidence, shall be conclusive, and its recommendation, if any, for the modification or setting aside of its original order, with the return of such

additional evidence. The judgment and decree of the court shall be final, except that the same shall be subject to review by the Supreme Court upon certiorari, as provided in section 347 of Title 28.

Jurisdiction of court

(d) Upon the filing of the record with it the jurisdiction of the court of appeals of the United States to affirm, enforce, modify, or set aside orders of the Commission shall be exclusive.

Precedence of proceedings; exemption from liability

(e) Such proceedings in the court of appeals shall be given precedence over other cases pending therein, and shall be in every way expedited. No order of the Commission or judgment of court to enforce the same shall in anywise relieve or absolve any person, partnership, or corporation from any liability under the Antitrust Acts.

Service of complaints, orders and other processes; return

(f) Complaints, orders, and other processes of the Commission under this section may be served by anyone duly authorized by the Commission, either (a) by delivering a copy thereof to the person to be served, or to a member of the partnership to be served, or the president, secretary, or other executive officer or a director of the corporation to be served; or (b) by leaving a copy thereof at the residence or the principal office or place of business of such person, partnership, or corporation; or (c) by mailing a copy thereof by registered mail or by certified mail addressed to such person, partnership, or corporation at his or its residence or principal office or place of business. The verified return by the person so serving said complaint, order, or other process setting forth the manner of said service shall be proof of the same, and the return post office receipt for said complaint, order, or other process mailed by registered mail or by certified mail as aforesaid shall be proof of the service of the same.

Finality of order

(g) An order of the Commission to cease and desist shall become final—

(1) Upon the expiration of the time allowed for filing a petition for review, if no such petition has been duly filed within such time; but the Commission may thereafter modify or set aside its order to the extent provided in the last sentence of subsection (b); or

(2) Upon the expiration of the time allowed for filing a petition for certiorari, if the order of the Commission has been affirmed, or the petition for review dismissed by the court of appeals, and no petition for certiorari has been duly filed; or

(3) Upon the denial of a petition for certiorari, if the order of the Commission has been affirmed or the petition for review dismissed by the court of appeals; or

(4) Upon the expiration of thirty days from the date of issuance of the mandate of the Supreme Court, if such Court directs that the order of the Commission be affirmed or the petition for review dismissed.

Same; order modified or set aside by Supreme Court

(h) If the Supreme Court directs that the order of the Commission be modified or set aside, the order of the Commission rendered in accordance with the mandate of the Supreme Court shall become final upon the expiration of thirty days from the time it was rendered, unless within such thirty days either party has instituted proceedings to have such order corrected to accord with the mandate, in which event the order of the Commission shall become final when so corrected.

Same; order modified or set aside by Court of Appeals

(i) If the order of the Commission is modified or set aside by the court of appeals, and if (1) the time allowed for filing a petition for certiorari has expired and no such petition has been duly filed, or (2) the petition for certiorari has been denied, or (3) the decision of the court has been affirmed by the Supreme Court, then the order of the Commission rendered in accordance with the mandate of the court of appeals shall become final on the expiration of thirty days from the time such order of the Commission was rendered, unless within such thirty days either party has instituted proceedings to have such order corrected so that it will accord with the mandate, in which event the order of the Commission shall become final when so corrected.

Same; rehearing upon order or remand

(j) If the Supreme Court orders a rehearing; or if the case is remanded by the court of appeals to the Commission for a rehearing, and if (1) the time allowed for filing a petition for certiorari has expired, and no such petition has been duly filed, or (2) the petition for certiorari has been denied, or (3) the decision of the court has been affirmed by the Supreme Court, then the order of the Commission rendered upon such rehearing shall become final in the same manner as though no prior order of the Commission had been rendered.

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Definition of mandate

(k) As used in this section the term "mandate", in case a mandate has been recalled prior to the expiration of thirty days from the date of issuance thereof, means the final mandate.

Penalty for violation of order; injunctions and other appropriate equitable relief

(*l*) Any person, partnership, or corporation who violates an order of the Commission after it has become final, and while such order is in effect, shall forfeit and pay to the United States a civil penalty of not more than $10,000 for each violation, which shall accrue to the United States and may be recovered in a civil action brought by the Attorney General of the United States. Each separate violation of such an order shall be a separate offense, except that in the case of a violation through continuing failure to obey or neglect to obey a final order of the Commission, each day of continuance of such failure or neglect shall be deemed a separate offense. In such actions, the United States district courts are empowered to grant mandatory injunctions and such other and further equitable relief as they deem appropriate in the enforcement of such final orders of the Commission.

Civil actions for recovery of penalties for knowing violations of rules and cease and desist orders respecting unfair or deceptive acts or practices; jurisdiction; maximum amount of penalties; continuing violations; de novo determinations; compromise or settlement procedure

(m)(1)(A) The Commission may commence a civil action to recover a civil penalty in a district court of the United States against any person, partnership, or corporation which violates any rule under this chapter respecting unfair or deceptive acts or practices (other than an interpretive rule or a rule violation of which the Commission has provided is not an unfair or deceptive act or practice in violation of subsection (a)(1) of this section) with actual knowledge or knowledge fairly implied on the basis of objective circumstances that such act is unfair or deceptive and is prohibited by such rule. In such action, such person, partnership, or corporation shall be liable for a civil penalty of not more than $10,000 for each violation.

(B) If the Commission determines in a proceeding under subsection (b) of this section that any act or practice is unfair or deceptive, and issues a final cease and desist order with respect to such act or practice, then the Commission may commence a civil action to obtain a civil penalty in a district court of the United States against any person, partnership, or corporation which engages in such act or practice—

(1) after such cease and desist order becomes final (whether or not such person, partnership, or corporation was subject to such cease and desist order), and

(2) with actual knowledge that such act or practice is unfair or deceptive and is unlawful under subsection (a)(1) of this section.

In such action, such person, partnership, or corporation shall be liable for a civil penalty of not more than $10,000 for each violation.

(C) In the case of a violation through continuing failure to comply with a rule or with subsection (a)(1) of this section, each day of continuance of such failure shall be treated as a separate violation, for purposes of subparagraphs (A) and (B). In determining the amount of

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such a civil penalty, the court shall take into account the degree of culpability, any history of prior such conduct, ability to pay, effect on ability to continue to do business, and such other matters as justice may require.

(2) If the cease and desist order establishing that the act or practice is unfair or deceptive was not issued against the defendant in a civil penalty action under paragraph (1)(B) the issues of fact in such action against such defendant shall be tried de novo.

(3) The Commission may compromise or settle any action for a civil penalty if such compromise or settlement is accompanied by a public statement of its reasons and is approved by the court.

As amended Nov. 16, 1973, Pub.L. 93–153, Title IV, § 408(c), (d), 87 Stat. 591, 592; Jan. 4, 1975, Pub.L. 93–637, Title II, §§ 201(a), 204(b), 205(a), 88 Stat. 2193, 2200; Dec. 12, 1975, Pub.L. 94–145, § 3, 89 Stat. 801.

APPENDIX C — FEDERAL ADVISORY COMMITTEE ACT, 5 APP. I SECTION 1, *ET SEQ.*

§ 1. Short title

This Act may be cited as the "Federal Advisory Committee Act".

§ 2. Findings and purpose

(a) The Congress finds that there are numerous committees, boards, commissions, councils, and similar groups which have been established to advise officers and agencies in the executive branch of the Federal Government and that they are frequently a useful and beneficial means of furnishing expert advice, ideas, and diverse opinions to the Federal Government.

(b) The Congress further finds and declares that—

(1) the need for many existing advisory committees has not been adequately reviewed;

(2) new advisory committees should be established only when they are determined to be essential and their number should be kept to the minimum necessary;

(3) advisory committees should be terminated when they are no longer carrying out the purposes for which they were established;

(4) standards and uniform procedures should govern the establishment, operation, administration, and duration of advisory committees;

(5) the Congress and the public should be kept informed with respect to the number, purpose, membership, activities, and cost of advisory committees; and

(6) the function of advisory committees should be advisory only, and that all matters under their consideration should be determined, in accordance with law, by the official, agency, or officer involved.

§ 3. Definitions.

For the purpose of this Act—

(1) The term "Director" means the Director of the Office of Management and Budget.

(2) The term "advisory committee" means any committee, board, commission, council, conference, panel, task force, or other similar group, or any subcommittee or other subgroup thereof (hereafter in this paragraph referred to as "committee"), which is—

(A) established by statute or reorganization plan, or

(B) established or utilized by the President, or

(C) established or utilized by one or more agencies,

in the interest of obtaining advice or recommendations for the President or one or more agencies or officers of the Federal Government, except that such term excludes (i) the Advisory Commission on Intergovernmental Relations, (ii) the Commission on Government Procurement, and (iii) any committee which is composed wholly of full-time officers or employees of the Federal Government.

(3) The term "agency" has the same meaning as in section 551 (1) of Title 5.

(4) The term "Presidential advisory committee" means an advisory committee which advises the President.

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§ 4. Applicability; restrictions

(a) The provisions of this Act or of any rule, order, or regulation promulgated under this Act shall apply to each advisory committee except to the extent that any Act of Congress establishing any such advisory committee specifically provides otherwise.

(b) Nothing in this Act shall be construed to apply to any advisory committee established or utilized by—

(1) the Central Intelligence Agency; or

(2) the Federal Reserve System.

(c) Nothing in this Act shall be construed to apply to any local civic group whose primary function is that of rendering a public service with respect to a Federal program, or any State or local committee, council, board, commission, or similar group established to advise or make recommendations to State or local officials or agencies.

§ 5. Responsibilities of Congressional committees; review; guidelines

(a) In the exercise of its legislative review function, each standing committee of the Senate and the House of Representatives shall make a continuing review of the activities of each advisory committee under its jurisdiction to determine whether such advisory committee should be abolished or merged with any other advisory committee, whether the responsibilities of such advisory committee should be revised, and whether such advisory committee performs a necessary function not already being performed. Each such standing committee shall take appropriate action to obtain the enactment of legislation necessary to carry out the purpose of this subsection.

(b) In considering legislation establishing, or authorizing the establishment of any advisory committee, each standing committee of the Senate and of the House of Representatives shall determine, and report such determination to the Senate or to the House of Representatives, as the case may be, whether the functions of the proposed advisory committee are being or could be performed by one or more agencies or by an advisory committee already in existence, or by enlarging the mandate of an existing advisory committee. Any such legislation shall—

(1) contain a clearly defined purpose for the advisory committee;

(2) require the membership of the advisory committee to be fairly balanced in terms of the points of view represented and the functions to be performed by the advisory committee;

(3) contain appropriate provisions to assure that the advice and recommendations of the advisory committee will not be inappropriately influenced by the appointing authority or by any special interest, but will instead be the result of the advisory committee's independent judgment;

(4) contain provisions dealing with authorization of appropriations, the date for submission of reports (if any), the duration of the advisory committee, and the publication of reports and other materials, to the extent that the standing committee determines the provisions of section 10 of this Act to be inadequate; and

(5) contain provisions which will assure that the advisory committee will have adequate staff (either supplied by an agency or employed by it), will be provided adequate quarters, and will have funds available to meet its other necessary expenses.

(c) To the extent they are applicable, the guidelines set out in subsection (b) of this section shall be followed by the President, agency heads, or other Federal officials in creating an advisory committee.

§ 6. Responsibilities of the President; report to Congress; annual report to Congress; exclusion

(a) The President may delegate responsibility for evaluating and taking action, where appropriate, with respect to all public recommendations made to him by Presidential advisory committees.

(b) Within one year after a Presidential advisory committee has submitted a public report to the President, the President or his delegate shall make a report to the Congress stating either his proposals for action or his reasons for inaction, with respect to the recommendations contained in the public report.

(c) The President shall, not later than March 31 of each calendar year (after the year in which this Act is enacted), make an annual report to the Congress on the activities, status, and changes in the composition of advisory committees in existence during the preceding calendar year. The report shall contain the name of every advisory committee, the date of and authority for its creation, its termination date or the date it is to make a report, its functions, a reference to the reports it has submitted, a statement of whether it is an ad hoc or continuing body, the dates of its meetings, the names and occupations of its current members, and the total estimated annual cost to the United States to fund, service, supply, and maintain such committee. Such report shall include a list of those advisory committees abolished by the President, and in the case of advisory committees established by statute, a list of those advisory committees which the President recommends be abolished together with his reasons therefor. The President shall exclude from this report any information which, in his judgment, should be withheld for reasons of national security, and he shall include in such report a statement that such information is excluded.

§ 7. Responsibilities of the Director, Office of Management and Budget; Committee Management Secretariat, establishment; review; recommendations to President and Congress; agency cooperation; performance guidelines; uniform pay guidelines; travel expenses; expense recommendations

(a) The Director shall establish and maintain within the Office of Management and Budget a Committee Management Secretariat, which shall be responsible for all matters relating to advisory committees.

(b) The Director shall, immediately after October 6, 1972, institute a comprehensive review of the activities and responsibilities of each advisory committee to determine—

(1) whether such committee is carrying out its purpose;

(2) whether, consistent with the provisions of applicable statutes, the responsibilities assigned to it should be revised;

(3) whether it should be merged with other advisory committees; or

(4) whether is should be abolished.

The Director may from time to time request such information as he deems necessary to carry out his functions under this subsection. Upon the completion of the Director's review he shall make recommendations to the President and to either the agency head or the Congress with respect to action he believes should be taken. Thereafter, the Director shall carry out a similar review annually. Agency heads shall cooperate with the Director in making the reviews required by this subsection.

(c) The Director shall prescribe administrative guidelines and management controls applicable to advisory committees, and, to the maximum extent feasible, provide advice, assistance, and guidance to advisory committees to improve their performance. In carrying out his functions under this subsection, the Director shall consider the recommendations of each agency head with respect to means of improving the performance of advisory committees whose duties are related to such agency.

(d) (1) The Director, after study and consultation with the Civil Service Commission, shall establish guidelines with respect to uniform fair rates of pay for comparable services of members, staffs, and consultants of advisory committees in a manner which gives appropriate recognition to the responsibilities and qualifications required and other relevant factors. Such regulations shall provide that—

(A) no member of any advisory committee or of the staff of any advisory committee shall receive compensation at a rate in excess of the rate specified for GS–18 of the General Schedule under section 5332 of Title 5; and

(B) such members, while engaged in the performance of their duties away from their homes or regular places of business, may be allowed travel expenses, including per diem in lieu of subsistence, as authorized by section 5703 of Title 5, for persons employed intermittently in the Government service.

(2) Nothing in this subsection shall prevent—

(A) an individual who (without regard to his service with an advisory committee) is a full-time employee of the United States, or

(B) an individual who immediately before his service with an advisory committee was such an employee,

from receiving compensation at the rate at which he otherwise would be compensated (or was compensated) as a full-time employee of the United States.

(e) The Director shall include in budget recommendations a summary of the amounts he deems necessary for the expenses of advisory committees, including the expenses for publication of reports where appropriate.

§ 8. Responsibilities of agency heads; Advisory Committee Management Officer, designation

(a) Each agency head shall establish uniform administrative guidelines and management controls for advisory committees established by that agency, which shall be consistent with directives of the Director under section 7 and section 10. Each agency shall maintain systematic information on the nature, functions, and operations of each advisory committee within its jurisdiction.

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(b) The head of each agency which has an advisory committee shall designate an Advisory Committee Management Officer who shall—

(1) exercise control and supervision over the establishment, procedures, and accomplishments of advisory committees established by that agency;

(2) assemble and maintain the reports, records, and other papers of any such committee during its existence; and

(3) carry out, on behalf of that agency, the provisions of section 552 of Title 5, with respect to such reports, records, and other papers.

§ 9. Establishment and purpose of advisory committees; publication in Federal Register; charter: filing, contents, copy

(a) No advisory committee shall be established unless such establishment is—

(1) specifically authorized by statute or by the President; or

(2) determined as a matter of formal record, by the head of the agency involved after consultation with the Director, with timely notice published in the Federal Register, to be in the public interest in connection with the performance of duties imposed on that agency by law.

(b) Unless otherwise specifically provided by statute or Presidential directive, advisory committees shall be utilized solely for advisory functions. Determinations of action to be taken and policy to be expressed with respect to matters upon which an advisory committee reports or makes recommendations shall be made solely by the President or an officer of the Federal Government.

(c) No advisory committee shall meet or take any action until an advisory committee charter has been filed with (1) the Director, in the case of Presidential advisory committees, or (2) with the head of the agency to whom any advisory committee reports and with the standing committees of the Senate and of the House of Representatives having legislative jurisdiction of such agency. Such charter shall contain the following information:

(A) the committee's official designation;

(B) the committee's objectives and the scope of its activity;

(C) the period of time necessary for the committee to carry out its purposes;

(D) the agency or official to whom the committee reports;

(E) the agency responsible for providing the necessary support for the committee;

(F) a description of the duties for which the committee is responsible, and, if such duties are not solely advisory, a specification of the authority for such functions;

(G) the estimated annual operating costs in dollars and man-years for such committee;

(H) the estimated number and frequency of committee meetings;

(I) the committee's termination date, if less than two years from the date of the committee's establishment; and

(J) the date the charter is filed.

A copy of any such charter shall also be furnished to the Library of Congress.

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§ 10. Advisory committee procedures; meetings; notice, publication in Federal Register; regulations; minutes; certification; annual report; Federal officer or employee, attendance

(a) (1) Each advisory committee meeting shall be open to the public.

(2) Except when the President determines otherwise for reasons of national security, timely notice of each such meeting shall be published in the Federal Register, and the Director shall prescribe regulations to provide for other types of public notice to insure that all interested persons are notified of such meeting prior thereto.

(3) Interested persons shall be permitted to attend, appear before, or file statements with any advisory committee, subject to such reasonable rules or regulations as the Director may prescribe.

(b) Subject to section 552 of Title 5, the records, reports, transcripts, minutes, appendixes, working papers, drafts, studies, agenda, or other documents which were made available to or prepared for or by each advisory committee shall be available for public inspection and copying at a single location in the offices of the advisory committee or the agency to which the advisory committee reports until the advisory committee ceases to exist.

(c) Detailed minutes of each meeting of each advisory committee shall be kept and shall contain a record of the persons present, a complete and accurate description of matters discussed and conclusions reached, and copies of all reports received, issued, or approved by the advisory committee. The accuracy of all minutes shall be certified to by the chairman of the advisory committee.

(d) Subsections (a)(1) and (a)(3) of this section shall not apply to any portion of an advisory committee meeting where the President, or the head of the agency to which the advisory committee reports, determines that such portion of such meeting may be closed to the public in accordance with subsection (c) of section 552b of Title 5. Any such determination shall be in writing and shall contain the reasons for such determination. If such a determination is made, the advisory committee shall issue a report at least annually setting forth a summary of its activities and such related matters as would be informative to the public consistent with the policy of section 552(b) of Title 5.

(e) There shall be designated an officer or employee of the Federal Government to chair or attend each meeting of each advisory committee. The officer or employee so designated is authorized, whenever he determines it to be in the public interest, to adjourn any such meeting. No advisory committee shall conduct any meeting in the absence of that officer or employee.

(f) Advisory committees shall not hold any meetings except at the call of, or with the advance approval of, a designated officer or employee of the Federal Government, and in the case of advisory committees (other than Presidential advisory committees), with an agenda approved by such officer or employee.

As amended Pub.L. 94–409, § 5(c), Sept. 13, 1976, 90 Stat. 1247.

§ 11. Availability of transcripts; "agency proceeding"

(a) Except where prohibited by contractual agreements entered into prior to the effective date of this Act, agencies and advisory committees

shall make available to any person, at actual cost of duplication, copies of transcripts of agency proceedings or advisory committee meetings.

(b) As used in this section "agency proceeding" means any proceeding as defined in section 551(12) of Title 5.

References in Text. Effective date of this Act, referred to in subsec. (a), as meaning effective upon expiration of ninety days following enactment of Pub. L. 92-463 on Oct. 6, 1972, see section 15 of Pub.L. 92-463.

1. Standing to sue

Any person whose request for information under this appendix had been denied has standing to sue for the information: Center for Auto Safety v. Tiemann, D.C. D.C.1976, 414 F.Supp. 215, remanded on other grounds 580 F.2d 689, 188 U.S.App. D.C. 428.

§ 12. Fiscal and administrative provisions; recordkeeping; audit; agency support services

(a) Each agency shall keep records as will fully disclose the disposition of any funds which may be at the disposal of its advisory committees and the nature and extent of their activities. The General Services Administration, or such other agency as the President may designate, shall maintain financial records with respect to Presidential advisory committees. The Comptroller General of the United States, or any of his authorized representatives, shall have access, for the purpose of audit and examination, to any such records.

(b) Each agency shall be responsible for providing support services for each advisory committee established by or reporting to it unless the establishing authority provides otherwise. Where any such advisory committee reports to more than one agency, only one agency shall be responsible for support services at any one time. In the case of Presidential advisory committees, such services may be provided by the General Services Administration.

§ 13. Responsibilities of Library of Congress; reports and background papers; depository

Subject to section 552 of Title 5, the Director shall provide for the filing with the Library of Congress of at least eight copies of each report made by every advisory committee and, where appropriate, background papers prepared by consultants. The Librarian of Congress shall establish a depository for such reports and papers where they shall be available to public inspection and use.

§ 14. Termination of advisory committees; renewal; continuation

(a) (1) Each advisory committee which is in existence on the effective date of this Act shall terminate not later than the expiration of the two-year period following such effective date unless—

(A) in the case of an advisory committee established by the President or an officer of the Federal Government, such advisory committee is renewed by the President or that officer by appropriate action prior to the expiration of such two-year period; or

(B) in the case of an advisory committee established by an Act of Congress, its duration is otherwise provided for by law.

(2) Each advisory committee established after such effective date shall terminate not later than the expiration of the two-year period beginning on the date of its establishment unless—

(A) in the case of an advisory committee established by the President or an officer of the Federal Government such advisory committee is renewed by the President or such officer by appropriate action prior to the end of such period; or

(B) in the case of an advisory committee established by an Act of Congress, its duration is otherwise provided for by law.

(b) (1) Upon the renewal of any advisory committee, such advisory committee shall file a charter in accordance with section 9(c).

(2) Any advisory committee established by an Act of Congress shall file a charter in accordance with such section upon the expiration of each successive two-year period following the date of enactment of the Act establishing such advisory committee.

(3) No advisory committee required under this subsection to file a charter shall take any action (other than preparation and filing of such charter) prior to the date on which such charter is filed.

(c) Any advisory committee which is renewed by the President or any officer of the Federal Government may be continued only for successive two-year periods by appropriate action taken by the President or such officer prior to the date on which such advisory committee would otherwise terminate.

§ 15. Effective date

Except as provided in section 7(b), this Act shall become effective upon the expiration of ninety days following October 6, 1972.

No. 79-731

In the Supreme Court of the United States

OCTOBER TERM, 1979

PORTER & DIETSCH, INC., ET AL., PETITIONERS

v.

FEDERAL TRADE COMMISSION

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE SEVENTH CIRCUIT

BRIEF FOR THE FEDERAL TRADE COMMISSION IN OPPOSITION

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OPINIONS BELOW

The opinion (Pet. App. 1a-27a) of the court of appeals is reported at 605 F. 2d 294. The order and opinion of the Federal Trade Commission (Pet. App. 115a-145a) are reported at 90 F.T.C. 770.

JURISDICTION

The judgment of the court of appeals was entered on August 8, 1979 (Pet. App. 1a). The petition for a writ of certiorari was filed on November 6, 1979. The jurisdiction of this Court is invoked under 28 U.S.C. 1254(1).

QUESTIONS PRESENTED

1. Whether the Federal Trade Commission properly required petitioners to make certain disclosures in their advertisements for weight-reduction preparations.

2. Whether the Commission properly prohibited petitioners from making performance claims for certain products unless such claims are fully and completely substantiated by competent scientific studies.

3. Whether the Commission was estopped by other agency proceedings from determining the safety and efficacy of petitioners' product.

4. Whether Commissioners who were absent from oral argument could participate in the Commission's decision in this case.

STATEMENT

1. Petitioner Porter & Dietsch, Inc., markets "X-11" tablets containing phenylpropanolamine hydrochloride ("PPA"), a mild appetite suppressant.[1] It buys the tablets from a manufacturer, packages them along with a leaflet that includes a low-calorie diet, and sells the package as the "X-11 Reducing Plan." The product is advertised and sold throughout the United States and is distributed through retail drug stores and by mail-order (Pet. App. 1a-2a, 43a).[2]

On complaint and after evidentiary hearings, the Federal Trade Commission found that petitioners had made numerous false statements in advertising X-11 tablets (Pet. App. 123a-129a).[3] First, petitioners falsely represented that users of X-11 tablets could lose weight

[1]Petitioner William Fraser is president of Porter & Dietsch, Inc., and its sole stockholder. Petitioner Kelly Ketting Furth was its advertising agency, and petitioner Joseph Furth was the account executive responsible for X-11 advertising (Pet. App. 1a-2a).

[2]See also *Pay 'N Save Corp.* v. *FTC*, petition for cert. pending, No. 79-1090.

[3]The Commission's decision adopted in large part the findings and conclusions of the administrative law judge (Pet. App. 37a-115a).

without restricting their normal caloric intake and while continuing to eat foods of their choice.[4] In reality, however, a person who wishes to lose weight in accordance with petitioners' representations while using X-11 tablets must also maintain a highly restrictive starvation or near-starvation diet and totally abstain from rich foods such as nuts, candy and pastry. Second, petitioners erroneously asserted that X-11 contains a unique ingredient, whereas PPA is an ingredient in a variety of other over-the-counter drug preparations. Third, petitioners falsely proclaimed that scientific evidence demonstrated that substantially all users of X-11 tablets will lose a significant amount of weight, when in fact most users will not experience substantial weight loss (Pet. App. 2a, 123a-129a).

Moreover, the Commission found that petitioners had failed to disclose various material facts in advertising X-11 tablets and that such omissions rendered the advertisements false and deceptive. Thus, petitioners did not report that the typical and ordinary experience of consumers does not parallel the experience reported in testimonials appearing in the advertisements[5] or that a highly restricted diet is a part of the X-11 plan. Further, the advertisements failed to indicate that persons with high blood pressure, heart disease, diabetes, or thyroid

[4]Typical claims included (Pet. App. 55a):

"WHY STARVE YOURSELF WHILE YOU REDUCE? EAT . . . AND LOSE THAT FAT."

"ENJOY EATING THE FOODS YOU CHOSE WHILE YOU LOSE EXCESS, UGLY FAT."

"EAT WHAT YOU WANT—AND SLIM DOWN."

[5]Advertisements frequently contained bold headlines such as "I USED TO WEIGH 160 LBS., NOW I'M DOWN TO 105" and "I LOST 80 LBS" (Pet. App. 46a, 117a).

disease should use X-11 tablets only as directed by a physician. The X-11 boxes carry such a warning, but the Commission concluded that the health hazard is "an important and material fact" that should be disclosed in the advertisements as well (Pet. App. 3a, 129a-131a).

2. In light of these extensive misrepresentations, the Commission ordered petitioners to cease their false and misleading advertising practices and also to make certain affirmative disclosures in the future (Pet. App. 141a-145a). The order prohibits petitioners from representing that their products[6] will bring about weight loss without dieting or that their products contain "unique ingredients," unless such claims are accurate (*id.* at 142a-143a). Similarly, the order prohibits use of product performance representations not substantiated by competent scientific or medical tests or studies and use of testimonials not indicative of typical user experience (*ibid.*). In addition, in advertising diet remedies such as the X-11 Plan, petitioners are now required to disclose that "Dieting is required" (*id.* at 143a). The Commission also ordered petitioners to warn consumers of the health risks associated with the X-11 Plan in all future advertising.[7] The order further states that these affirmative disclosures must be made in type size equivalent to the largest type size used in the particular printed advertisement (*ibid.*).

[6]The order covers any food, drug, cosmetic, or device (Pet. App. 142a). The Commission concluded that all these products should be covered because petitioner Porter & Dietsch, Inc., is constantly marketing new products, and because as a wholesaler, rather than a manufacturer, it can easily modify its product line (*id.* at 137a-138a).

[7]The advertisements must include the following statement (Pet. App. 143a): "Warning: This product poses a serious health risk for some users. Read the label carefully before using." The court of appeals modified this warning to read: "Warning: This product poses a serious health risk for users with high blood pressure, heart disease, diabetes, or thyroid disease. Read the label carefully before using" (Pet. App. 22a-23a).

3. The court of appeals enforced the order, with minor modifications (Pet. App. 1a-20a). It sustained the Commission's findings that petitioners repeatedly made false statements and omitted material facts in advertising the X-11 pills (Pet. App. 8a-15a). The court rejected petitioners' claims that the Commission's remedial order violated their First Amendment rights: "Because the advertising material subject to the Commission's order was false and misleading * * * it receives no protection from the First Amendment" (Pet. App. 16a).[8] In particular, the court of appeals approved the Commission's directive that petitioners' future product performance claims be substantiated by competent scientific or medical evidence. Relying on *FTC* v. *Colgate-Palmolive Co.*, 380 U.S. 374, 395 (1965), the court concluded that this requirement was an appropriate "fencing in" provision "justified * * * by the egregiousness of past representations and the propensity of [petitioners] to violate the [Federal Trade Commission] Act" (Pet. App. 19a). Likewise, the court upheld the Commission's decision to impose limited disclosure requirements on petitioners regarding their future advertising of diet products containing PPA. The court stated that these requirements are necessary to prevent deception and to protect public safety (*id.* at 20a-23a). See also note 7, *supra*.

[8]The court also concluded that the order properly encompassed petitioners' representations concerning any food, drug, cosmetic or device and not just X-11 tablets. The court correctly stated that petitioners Fraser and Porter & Dietsch's wholly-owned subsidiaries have violated the Federal Trade Commission Act in the past and that, as wholesalers, petitioners are able to add new product lines with relative ease (Pet. App. 16a-17a).

The court of appeals also rejected petitioners' procedural attacks on the proceedings before the Commission. Referring to the express provisions of 16 C.F.R. 3.52(f), the court held that two Commissioners who did not hear oral argument in this case but who reviewed a transcript of that argument properly participated in the decision (Pet. App. 3a-5a). The court noted that petitioners have "no cognizable interest in the composition of the tribunal that will decide [their] case and [are] entitled only to impartiality in that tribunal" (*id.* at 4a). In addition, the court concluded that the Commission was not collaterally estopped from litigating the issue of petitioners' false and misleading advertising regarding a product that poses a substantial risk to the public. The court explained that the "body of knowledge in the fields of medical and pharmacological science * * * is constantly increasing" and that the prior administrative decisions of the Postal Service upon which petitioners rely involved different distributors of a different, although similar dieting product (*id.* at 7a).

ARGUMENT

This case does not raise any significant issue meriting review by this Court. Petitioners do not directly challenge the concurrent findings of the Commission and the court of appeals that the X-11 advertising campaign was egregiously false and misleading,[9] and the courts

[9]We note, however, that petitioners seem to suggest (Pet. 6, 7, 13) that the conclusion of the court of appeals and the Commission regarding the misleading nature of petitioners' advertising has somehow been refuted by a recent determination of an FDA panel of experts that PPA may be an effective aid in appetite control. As the court of appeals observed, the modest conclusion, which has not yet been adopted by the FDA and which was made long after the false advertisements in question here, falls far short of substantiating the lavish claims about the X-11 product made by petitioners.

have repeatedly and consistently upheld the Commission's authority to require prior substantiation of advertising claims and disclosure of material information in false advertising cases such as this one. See, *e.g.*, *Jay Norris, Inc.* v. *FTC*, 598 F. 2d 1244 (2d Cir.), cert. denied, No. 79-434 (Dec. 3, 1979); *Warner-Lambert Co.* v. *FTC*, 562 F. 2d 749 (D.C. Cir. 1977), cert. denied, 435 U.S. 950 (1978). Moreover, the court of appeals correctly rejected petitioners' procedural claims in an extensive opinion that does not conflict with any decision of this Court or any court of appeals. In short, the court of appeals has properly applied well settled legal principles to the facts of this case, and further review is unwarranted.

1. Petitioners first contend (Pet. 11-13) that the affirmative disclosures required by the Commission effectively constitute a total ban on their advertising, in violation of the First Amendment. The First Amendment, however, affords commercial speech only a limited measure of protection. See, *e.g.*, *Friedman* v. *Rogers*, 440 U.S. 1, 9-11 & n.9 (1979); *Ohralik* v. *Ohio State Bar Ass'n*, 436 U.S. 447, 455-456 (1978); *Bates* v. *State Bar of Arizona*, 433 U.S. 350, 383 (1977). In particular, the government has broad power to restrict potentially false, deceptive, or misleading commercial speech. See, *e.g.*, *Friedman* v. *Rogers*, *supra*, 440 U.S. at 9; *Bates* v. *State Bar of Arizona*, *supra*, 433 U.S. at 383-384; *Virginia Pharmacy Board* v. *Virginia Citizens Consumer Council*, 425 U.S. 748, 771-772 & n.24 (1976). Thus, as petitioners appear to recognize (Pet. 11-12), there is no doubt that the Commission may constitutionally order affirmative disclosures and warnings in advertising so long as the relief represents a reasonable method of correcting past deceptions and preventing future ones. *National Society of Professional Engineers* v. *United States*, 435 U.S. 679,

698 (1978); *Bates* v. *State Bar of Arizona*, *supra*, 433 U.S. at 384; *Virginia Citizens Consumer Council*, *supra*, 425 U.S. at 772 n.24; *National Comm'n on Egg Nutrition* v. *FTC*, 570 F. 2d 157, 160-162 (7th Cir. 1977), cert. denied, 439 U.S. 821 (1978); *Warner-Lambert Co.* v. *FTC*, *supra*, 562 F. 2d at 758-763.

It is thus apparent that the affirmative warnings ordered here are well within constitutional limits. Both the court of appeals and the Commission found that petitioners had repeatedly made false and misleading statements about the efficacy and safety of their product. The dieting and health disclosures formulated by the Commission in direct response to those deceptions are an appropriate means of avoiding similarly misleading advertising in the future. *National Comm'n on Egg Nutrition* v. *FTC*, *supra*; *Warner-Lambert Co.* v. *FTC*, *supra*; *J.B. Williams Co.* v. *FTC*, 381 F. 2d 884 (6th Cir. 1967); *Ward Laboratories, Inc.* v. *FTC*, 276 F. 2d 952 (2d Cir.), cert. denied, 364 U.S. 827 (1960). Moreover, requiring the disclosure and warning to be in the same type size as the largest type used in the particular advertisement ensures that the public will be fully protected and that petitioners, who have previously gone to the limits of the law and beyond (Pet. App. 17a), cannot nullify the disclosure requirement by hiding the dieting and health warnings in the remainder of the advertisement. See *National Comm'n on Egg Nutrition* v. *FTC*, *supra*, 570 F. 2d at 160; *Warner-Lambert Co.* v.

FTC, *supra*, 562 F. 2d at 763.[10] That these disclosure requirements may adversely affect petitioners' future sales simply reflects the materiality of those disclosures and the harm to the public previously caused by petitioners' misleading and deceptive sales methods.

2. Petitioners' claims (Pet. 13-14) regarding the substantiation requirement are also without merit. The Commission's order prohibits petitioners from making product performance claims unless those claims are

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[10]Contrary to petitioners' claim (Pet. 11), the decision in this case does not conflict with either *National Comm'n on Egg Nutrition*, *supra*, or *Warner-Lambert Co.*, *supra*. In the former case, the Seventh Circuit approved a Commission order that required certain disclosures to be made "clearly and conspicuously." 570 F. 2d at 160. The Commission order in that case did not specify what "clearly and conspicuously" meant in terms of type size and the court of appeals therefore had no occasion to consider that issue. Here, the Commission has quantified the "clearly and conspicuously" standard (Pet. App. 144a) and the Seventh Circuit has sustained the print size requirement. See also *Wisniewski* v. *United States*, 353 U.S. 901, 902 (1957) (the Court does not sit to resolve alleged intra-circuit conflicts).

Similarly, in *Warner-Lambert Co.*, the court of appeals upheld a Commission order requiring that certain disclosures be made "in type size at least as large as * * * the principle portion of the text" and "separated from the text so that it can be readily noticed." 562 F. 2d at 763. The court did not suggest that a larger type requirement would be inappropriate in that or any other case. To the contrary, the opinion elsewhere states that stricter requirements "might be called for in an egregious case of deliberate deception, but this is not one." *Ibid.* Here, in contrast, the court of appeals specifically observed that the Commission's order is "justified in this case by the egregiousness of past representations and the propensity of [petitioners] to violate the Act" (Pet. App. 19a). Moreover, there is a substantial question whether the order in this case is in fact more strict that that involved in *Warner-Lambert*, since although the print size requirement here may be somewhat larger, there is no requirement that the disclosures or warnings be conspicuously separated from the text of the advertisement.

substantiated by competent scientific tests or studies (Pet. App. 142a). The order does not, however, "require petitioners to conduct needless tests" (Pet. 13). To the extent that petitioners modify their claims about the X-11 Plan so that existing, competent tests or studies support those claims, petitioners will not have to conduct any additional tests; the terms of the order will be satisfied if they gather existing documentation that is sufficient to support their modified claims and make it available to the Commission for inspection. Petitioners will be required to conduct their own studies only if they wish to make claims that are not supported by any existing studies of a particular product[11] or if they decide to market products for which efficacy and safety data have not yet been developed.

Section 5 of the Federal Trade Commission Act, 15 U.S.C. 45, prohibits all advertisers from making performance representations that are unsubstantiated. See *e.g.*, *Jay Norris, Inc.* v. *FTC*, *supra*, 598 F. 2d at 1250. And where, as here, an advertiser has violated the Act in this regard, the courts of appeals have repeatedly concluded that the Commission may impose a substantiation requirement on the advertiser, such as that at issue here. See, *e.g.*, *Jay Norris, Inc.* v. *FTC*, *supra*; *Tashof* v. *FTC*, 437 F. 2d 707, 715 (D.C. Cir. 1970). As this Court explained in *FTC* v. *Colgate-Palmolive Co.*, 380 U.S. 374, 395 (1965):

> We think it reasonable for the Commission to frame its order broadly enough to prevent respondents from engaging in similarly illegal practices in future

[11]The recent FDA study on which petitioners rely (see note 9, *supra*) simply does not substantiate petitioners' claims that the X-11 pills will result in weight loss without dieting or that substantially all users of the X-11 pill will lose weight. See Pet. App. 12a n.6.

> advertisements. As was said in *Federal Trade Comm'n* v. *Ruberoid Co.*, 343 U.S. 470, 473: "[t]he Commission is not limited to prohibiting the illegal practice in the precise form in which it is found to have existed in the past." Having been caught violating the Act, respondents "must expect some fencing in." *Federal Trade Comm'n* v. *National Lead Co.*, 352 U.S. 419, 431.

See also *Jacob Siegel Co.* v. *FTC*, 327 U.S. 608, 611-613 (1946) ("The Commission has wide discretion in its choice of a remedy * * *.").

3. Petitioners further contend (Pet. 14-16) that principles of collateral estoppel preclude the FTC from litigating the efficacy and safety of their product. Petitioners primarily rely on a Postal Service decision regarding another advertiser's dieting product similar to that marketed by petitioners. See *In re Hanover House and Romar Sales Corp.*, Post. Serv. Docket Nos. 2/143 and 2/149 (1975) (J.A. 261-274).[12] But that proceeding involved substantially different advertising claims[13] and

[12]Petitioners also point to the Commission's earlier decision in *In re Allegheny Pharmacal Corp.*, 75 F.T.C. 990 (1969). The court of appeals correctly stated that *Allegheny* "involved issues different from those in the case at bar" (Pet. App. 7a). Further, the Commission specifically dismissed that proceeding without a final decision on the merits and without prejudice to further Commission action (75 F.T.C. at 1036). Such a decision does not constitute a basis for estoppel. See, *e.g.*, *Lawlor* v. *National Screen Service Corp.*, 349 U.S. 322, 326 (1955); *C.G. Conn* v. *NLRB*, 108 F. 2d 390, 392-393 (7th Cir. 1939); K. Davis, *Administrative Law Text* § (3d ed. 1972).

[13]The advertisers in the Postal Service proceeding claimed that their product (Hungrex) would "banish hunger pains," would "cause calorie intake to go down," and would "help the user to start losing weight the first day" (J.A. 266-267). These assertions are far more modest than petitioners' claims that X-11 would result in substantial weight loss for all users and that users could eat anything that they wished to eat and still lose weight.

was brought under a significantly different statute.[14] In other words, neither the same issues nor the same facts that are the subject of this litigation were determined in the prior administrative hearing. Accordingly, the Commission was not collaterally estopped from proceeding against petitioners. See, *e.g.*, *Montana* v. *United States*, 440 U.S. 147, 155-162 (1979); *Parklane Hosiery Co.* v. *Shore*, 439 U.S. 322, 326 (1979); *Lawlor* v. *National Screen Service Corp.*, 349 U.S. 322, 326 (1955); *Brandenfels* v. *Day*, 316 F. 2d 375, 378 (D.C. Cir.), cert. denied, 375 U.S. 824 (1963); *United States* v. *42 Jars, More or Less*, 264 F. 2d 666, 668-669 (3d Cir. 1959).[15]

4. Finally, petitioners erroneously argue (Pet. 16-18) that two of the five Commissioners should not have participated in the decision of this case. Although Commissioner Dole was on leave and Chairman Pertschuk was not yet appointed at the time of oral argument in this case, both were active Commission members long before the Commission's decision was

[14]The Postal Service proceedings were based on 39 U.S.C. 3005, which provides that the Postal Service may prohibit the use of the mails to "conduct[] a scheme or device for obtaining money or property * * * by means of false representations * * *." Section 5(a) of the Federal Trade Commission Act, on the other hand, makes all "deceptive or unfair acts" unlawful (15 U.S.C. 45(a)), and thus encompasses a broader category of activities than does 39 U.S.C. 3005. See *Brandenfels* v. *Day*, 316 F. 2d 375, 378 (D.C. Cir.), cert. denied, 375 U.S. 824 (1963).

[15]Furthermore, even if the Postal Service proceeding did involve the same legal issue and the same advertising claims, the government is not precluded from relitigating in good faith an issue of public health dependent upon the "constantly increasing" "body of knowledge in the fields of medical and pharmacological science" (Pet. App. 7a). Cf. *FTC* v. *Raladam Co.*, 316 U.S. 149, 150-151 (1942); *Montana* v. *United States*, *supra*, 440 U.S. at 162-163.

rendered. Their participation was therefore proper under the Commission's rules, which expressly provide that Commissioners who are absent from oral argument may participate in the decision of the case where, as here, "the oral argument is stenographically reported" (16 C.F.R. 3.52(f); Pet. App. 3a-5a). Furthermore, it is well settled as a matter of both due process and administrative law that "a member of an administrative agency who did not hear oral argument may nevertheless participate in the decision where he has the benefit of the record before him." *Gearhart & Otis, Inc.* v. *SEC*, 348 F. 2d 798, 802 (D.C. Cir. 1965); see, *e.g.*, *Au Yi Lau* v. *INS*, 555 F. 2d 1036, 1042 (D.C. Cir. 1977); *Arthur Lipper Corp.* v. *SEC*, 547 F. 2d 171, 182-183 n.8 (2d Cir. 1976), cert. denied, 434 U.S. 1009 (1978); cf. *FCC* v. *WJR*, 337 U.S. 265, 274-277 (1949) (no due process right to oral argument).[16] That principle obtains even where a majority of the participating members become members after oral argument. See, *e.g.*, *Arthur Lipper Corp.* v. *SEC*, *supra*; *Au Yi Lau* v. *INS*, *supra*.

[16]Petitioners' reliance on *WIBC, Inc.* v. *FCC*, 259 F. 2d 941 (D.C. Cir.), cert. denied, 358 U.S. 920 (1958), is misplaced. In that case, oral argument was guaranteed by statute, whereas here the Commission's rules specifically permit a member to participate even though he has not heard oral argument. In any event, the District of Columbia Circuit has subsequently limited *WIBC, Inc.* to its peculiar facts. See *e.g.*, *Gearhart & Otis, Inc.* v. *SEC*, *supra*, 348 F. 2d at 802 n.14.

CONCLUSION

The petition for a writ of certiorari should be denied.

Respectfully submitted.

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